Compiled Public Comments on Request for Information on Draft NIH Biosafety Policy for Research Involving Biohazards

Notice Number: NOT-OD-26-112

August 19, 2026 – October 19, 2026

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1. Thomas E. Martin III

I am responding: On behalf of myself

Name: Thomas E. Martin III

Name of Organization: Elite Supply & Services, LLC - reessdata.com

Type of Organization: Professional Organization/Association

Role: Investigator/Researcher

Date Submitted: 8/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): reessdata.com

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope should explicitly recognize that biosafety depends not only on the biological agent or research activity, but also on the engineering controls and facility conditions that determine whether a biohazard is contained.
An important potential gap is oversight of real-world building and containment performance. Ventilation, directional airflow, room-pressure relationships, exhaust pathways, filtration, alarms, and related controls can affect exposure risk when biohazards are present.
I recommend that NIH ensure the policy covers failures or degradation of required engineering controls as part of biosafety oversight and requires objective verification that those controls perform as intended. Written assurances alone should not substitute for measured performance.
From my perspective as a patient with lifelong asthma and an indoor environmental quality background, this is especially important for workers, patients, research participants, and visitors with respiratory or other functional vulnerabilities.
You cannot effectively manage a biohazard if you do not also verify the systems intended to contain it.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered oversight is appropriate when it is calibrated to actual risk, but federal minimum requirements should apply wherever failure of containment could create significant risks to workers, research participants, patients, visitors, or the surrounding community.
Local institutions can manage routine implementation, but higher-risk activities should receive stronger independent oversight. Risk classification should consider not only the biohazard itself, but also the facility's engineering controls, fresh air ventilation / RH at 50% and containment requirements, potential consequences of equipment or building-system failure, and the vulnerability of potentially exposed populations.
Each tier should have clearly defined requirements for baseline “monitoring” verification, periodic

testing, incident and near-miss reporting, corrective actions, and escalation when controls fail.
A tiered system should not create different levels of protection simply because facilities are located in different jurisdictions. Federal oversight should establish and monitor the baseline in real time; local oversight should implement and strengthen it based on facility-specific risk.

3. Continued utility of Risk Groups: Risk Groups remain useful as a starting point, but they should not be the sole basis for determining appropriate oversight, particularly when an agent is genetically modified. Genetic modification can change characteristics relevant to risk, so assessment should consider the resulting organism and research activity rather than relying only on the Risk Group assigned to the original agent.
The BSL framework in the BMBL is also important because biosafety depends on how the work is actually conducted and contained. Oversight should therefore connect the biological risk assessment with the required practices, safety equipment, facility design, fresh air ventilation, relative humidity 50% directional airflow, pressure relationships, filtration, in/out/exchange exhaust, alarms, monitoring alerts, and other engineering controls.
I recommend a risk assessment → appropriate BSL/containment → objective verification approach.
When research changes the characteristics of an agent, the risk assessment and required containment should be reevaluated in real time, and critical engineering controls should be tested to verify that they perform as intended over time.
Classification identifies risk; monitoring performance helps verify and reduce risk = containment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should make voluntary compliance practical and valuable for institutions that are not formally subject to the policy.
A voluntary framework could provide standardized checklists, model Biosafety Assurances, risk-assessment tools, engineering-control verification guidance, incident and near-miss reporting templates, and training resources that institutions can adopt without excessive administrative burden.
NIH could also establish a voluntary recognition or reporting program for organizations that demonstrate compliance with these practices. Participation should emphasize measurable outcomes, including verification of required ventilation and containment controls, documentation of deficiencies, and completion of corrective actions.
Sharing de-identified lessons from incidents, near misses, engineering-control failures, and successful corrective actions could help institutions learn from one another.
The goal should be to make strong biosafety practices accessible beyond NIH-funded research: establish the baseline, verify the controls, document outcomes, and continuously improve.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The Incident Reporting and Meeting Minutes Templates should also account for patients with asthma, respiratory limitations, or environmental sensitivities when research activities occur in hospitals or healthcare facilities.
Negative-pressure rooms and zones serve important infection-control purposes, but may not be appropriate for every patient or circumstance. When a patient with asthma reports difficulty breathing or worsening symptoms, staff should promptly assess the patient, consider relocation to an appropriate environment when feasible, and provide supplemental oxygen by an appropriate delivery method when clinically indicated under applicable medical protocols.
Incident documentation should include room pressure, ventilation status, airflow, filtration and exhaust

performance, alarms, environmental measurements, symptoms, medical response, accommodations, corrective actions, and verification of engineering controls.
From my lived experience with lifelong asthma, the indoor parameters under which I function best are approximately:
Relative humidity (RH): 50%
Air temperature (AT): 68–72°F
CO_2: 400–600 ppm
VOCs: below 250 ppb
PM2.5 and PM1: as close to zero as reasonably achievable
I have found continuous indoor environmental monitoring and air-management equipment—including devices from Airthings, uHoo, and Dyson—valuable for comparing changes in my indoor environment with changes in my respiratory symptoms and functional ability. I provide these values as my individual observed parameters and accommodation information, not as proposed universal clinical thresholds or an endorsement of a particular manufacturer.
Incident reporting should preserve patient-specific environmental information so clinicians, biosafety personnel, facility professionals, and patients can compare measured conditions, symptoms, interventions, accommodations, and outcomes over time.
Measure the environment. Assess the patient. Verify the engineering controls. Accommodate individual respiratory needs.

6. Other feedback relevant to this resource: Additional implementation guidance would be beneficial on objective measurement, verification of engineering controls, and accommodations for workers, patients, research participants, and visitors with asthma, respiratory limitations, disabilities, or other environmental vulnerabilities.
NIH should provide practical guidance for establishing baseline facility conditions and periodically verifying ventilation, airflow, room-pressure relationships, filtration, exhaust, alarms, temperature, relative humidity, CO_2, VOCs, and particulate matter where these measurements are relevant to the facility and risk assessment.
Guidance should also explain what happens when measured conditions fall outside required parameters or when an individual reports respiratory symptoms or loss of function. There should be clear procedures for documenting the condition, assessing the individual, investigating potential environmental contributors, implementing corrective actions, considering reasonable accommodations or relocation, and verifying that controls are functioning properly before closing the matter.
For healthcare settings, additional guidance should address coordination among biosafety, infection prevention, facilities/engineering, occupational health, disability/accessibility personnel, and the patient's healthcare team. Negative-pressure environments may be necessary for infection control, but patient-specific respiratory needs should also be considered when determining an appropriate care environment.
Implementation resources should include standardized checklists, measurement and commissioning guidance, incident-reporting examples, accommodation procedures, corrective-action tracking, and training on interpreting environmental measurements without assuming that a single reading proves medical causation.
From my lived experience with lifelong asthma, measuring the environment alongside symptoms and functional changes can reveal patterns that would otherwise remain undocumented.
Establish the baseline. Monitor conditions. Listen to the patient. Correct deficiencies. Verify the results.

Uploaded File: III-Thomas_Martin_Indoo_Environmental_Health_Alert.pdf

Description: Patient-supplied conceptual illustration of fresh-air intake, stale-air exhaust, filtration and ventilation controls supporting healthier indoor environments for people with asthma and respiratory vulnerabilities.


REAL ESTATE CONNECTS:
HEALTH • ENERGY • AIR QUALITY • AFFORDABILITY • RESILIENCE
HEALTH
ENERGY
AIR QUALITY
AFFORDABILITY
RESILIENCE



LONG-TERM CARE IS REAL ESTATE WITH A HEALTH MISSION

Where accessibility, comfort, care, and verified building performance meet longevity.

Healthy housing should not be a luxury upgrade. It is longevity infrastructure.

REAL ESTATE CONNECTS

Health | Energy | Air Quality | Affordability | Resilience

Housing performance affects comfort, access, operating cost, and the ability to remain safely and independently at home. Families managing asthma, chemical sensitivity, chronic health conditions, fatigue, injury, or reduced mobility may also carry costs that ordinary housing comparisons do not show.

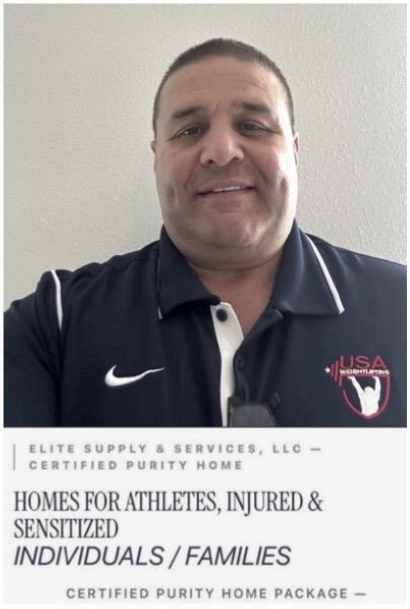
THE HIDDEN COST OF HOUSING

- HEPA and gas-phase filtration, filter replacement, and maintenance.
- Fresh-air ventilation, dehumidification, and energy needed to operate them.
- Indoor air monitoring, safer products, water treatment, and moisture control.
- Medical care, transportation, food, relocation risk, and lost usable space or time.

WHY MEASUREMENT MATTERS

A building can look acceptable while occupied-space conditions change by room, time, weather, equipment operation, and occupant activity. Continuous trend data helps residents ask better questions and document whether corrective actions produce measurable results.

> "My mission combines real-estate and indoor-environment experience with a health, vocational, and IWF/USA Weightlifting strength-and-conditioning perspective. I understand baseline performance, recovery, access needs, and the importance of measuring change over time."



Thomas E. Martin III

Elite Supply & Services, LLC | REESSData.com

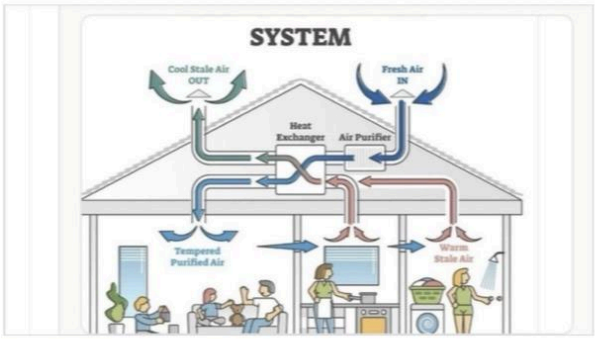
Homes for athletes, injured and sensitized individuals and families.

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INDOOR ENVIRONMENTAL HEALTH ALERT

Patient-documented conditions and function | Professional insight informed by lived experience



Conceptual system illustration supplied by the requester.

PURPOSE

To alert my primary-care provider and federal representatives that changes in indoor conditions have corresponded with measurable changes in my asthma symptoms and morning function. This single-patient observation requests documentation, research and verified building performance - not a claim of proven causation.

DOCUMENTED OVERNIGHT COMPARISON

08/15/2026 - controls not continuously effective

CO_2: **1,088 ppm** (peak about 1,246) | VOC: **789 ppb**
Morning: **L2-L3 symptoms and reduced function**, including wheeze and brain fog.

08/17/2026 - continuous overnight controls

Ventilation + filtration + dehumidification
CO_2: **574 ppm** | VOC: **132 ppb** | PM2.5: **2 ug/m3**
Morning: **No symptoms; asthma and productivity rated good.**

Interpretation: A temporal association in one patient - not proof of causation. CO_2 is a ventilation indicator, not a complete measure of indoor air quality.

EXAMPLES TO EVALUATE - VERIFY THE EXACT PRODUCT/SKU

TimberHP | ROCKWOOL | Knauf Insulation | Manson Insulation | CleanFiber
Also evaluate zero-/low-VOC paints, adhesives, cabinetry and sealants.

No blanket approvals or endorsements. Review product-specific emissions, ingredients, certifications and installation requirements.

PATIENT-INFORMED SYSTEM INSIGHT

As a patient with asthma since age 5 and an IEQ professional:
recirculation is not ventilation.
- Fans that only move room air do not add outdoor air.
- Outdoor air must reach occupied rooms; source areas need exhaust and transfer/return paths.
- Any patient-specific target, including 6 ACH, should distinguish outdoor-air ACH from filtration-based equivalent ACH and be professionally measured and verified.

CLINICAL + PCP ACTION

Medication remains important. If a trigger continues, medication alone may not fully control symptoms for some patients.

PCP: Document readings with symptoms and function; incorporate exposure reduction into the asthma plan; help clinicians understand accommodation needs.

CONGRESSIONAL ACTION

Support IEQ monitoring pilots; verified ventilation and moisture performance in federally supported housing and healthcare; and research involving medically vulnerable occupants.

Goal: Pair third-party macro verification with ongoing, occupant-visible monitoring and maintenance.

LIVED EXPERIENCE CAN REVEAL GAPS OTHERS MISS. Asthma and autism do not share one proven cause; study overlapping response patterns without assuming causation.

THOMAS E. MARTIN III Patient with asthma since age 5 | FL Mold Assessor MRSA #4055 | Founder, Elite Supply & Services, LLC

REESSData.com

Sources: U.S. EPA, How Outdoor Air Enters a Building; ASHRAE 62.2-2025; U.S. EPA, Asthma Triggers; U.S. EPA, Indoor airPLUS. Patient readings are monitor observations, not diagnostic tests. Prepared 08/19/2026.

2. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Government Agency

Role: Institutional Review Oversight Committee Member

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): medical countermeasures

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: NIH should clarify how biological toxin research is categorized when the toxin is used as a research material but is not genetically modified, propagated, or otherwise altered.
The final policy should clarify the review requirements for Select Agent-listed toxins maintained below Federal Select Agent Program exclusion quantities, including whether these activities require full IBC review solely because the toxin is listed or may qualify for delegated review based on risk.
NIH should clarify how detoxified, inactivated, modified, fragmented, or otherwise non-toxic toxin derivatives are treated under the policy.
NIH should further define the boundaries of "biomedical research" when applying the policy to non-NIH-funded research at institutions receiving NIH funding, particularly federal institutions operating under multiple missions and funding authorities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The tiered review framework is appropriate, but NIH should clarify whether an institutional risk assessment may support movement between review categories when the actual risk differs from the categorical assignment.
NIH should clarify whether Select Agent-listed toxins maintained below applicable exclusion quantities may qualify for delegated IBC review based on risk assessment.
NIH should define what constitutes equivalent oversight by another federal agency and identify which NIH requirements remain applicable when research is already subject to another federal biosafety oversight program.

3. Continued utility of Risk Groups: NIH should retain Risk Groups as a baseline hazard-assessment tool, while emphasizing that RG classification does not automatically determine the appropriate Biosafety Level.
Containment decisions should continue to be based on a comprehensive risk assessment considering the agent, genetic modifications, experimental procedures, quantities, routes of exposure, and available controls.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary adoption through readily available model procedures, risk-assessment tools, training materials, templates, and decision trees rather than creating unnecessary administrative requirements.
NIH should clarify whether voluntary adoption of the policy by an otherwise non-covered institution creates additional reporting, recordkeeping, public disclosure, or other compliance obligations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: NIH should provide specific guidance for public posting and redaction of IBC minutes and incident reports involving CUI, security-sensitive information, Select Agent security information, operational security, proprietary information, or other federally protected information.
Federal institutions should be permitted to use an alternative transparency mechanism when public posting conflicts with applicable security or information-protection requirements.
NIH should coordinate incident-reporting requirements with other federal oversight programs to minimize duplicative reporting of the same event.

6. Other feedback relevant to this resource: NIH should provide a comprehensive decision tree or flowchart for determining policy applicability and whether research requires NIH + IBC, full IBC, or delegated IBC review.
Implementation guidance should include examples involving Select Agent toxins above and below exclusion quantities, non-Select Agent toxins, detoxified/inactivated toxins, and medical countermeasure research.
NIH should provide additional examples involving viral vectors, plasmids, genetically modified organisms, cell lines, animal studies, and clinical research.
NIH should establish clear qualifications and documentation requirements for delegated IBC reviewers, including whether the Biosafety Officer may serve in this role.
NIH should provide standardized risk-assessment and Biosafety Assurance templates that institutions may adapt.
NIH should clarify transition requirements for currently approved research and research newly brought into scope under the expanded policy.
Additional implementation guidance should address institutions operating under multiple federal oversight frameworks and explain how equivalent federal oversight will be recognized.

3. Rawlston D. Crowther

I am responding: On behalf of myself

Name: Rawlston D. Crowther

Name of Organization: The City College City University of New York

Type of Organization: Academic Institution

Role: Other

Role - Other: EHOS Environmental Health and Occupational Safety

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

4. Nicole Ampadu

I am responding: On behalf of myself

Name: Nicole Ampadu

Name of Organization: New York University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The need for a BSO seems to have changed in this new policy. Previously a BSO was needed on a committee for large scale work, however now they are only needed for BSL3 and BSL 4 work or GDMOs. I don't agree with this logic since BSL2 materials can lead to LAIs . For this reason, I believe A BSL2 designation should be included under the responsibilities of a BSO as well.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): n/a

3. Continued utility of Risk Groups: n/a

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): n/a

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: n/a

6. Other feedback relevant to this resource: Question: Since this will replace the "NIH Guidelines...", will the older classifications ((III-(a-e), III-F, etc) change as well? This new policy has summarized and combined a lot into the new section IV.

5. Paul M. Arnaboldi

I am responding: On behalf of myself

Name: Paul M. Arnaboldi

Name of Organization: New York Medical College

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Broadly, infectious disease, neuroscience, cancer, and metabolic disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I find gaps in the policy that should be addressed in sections IV-1, 2, and 3:

In section IV-2: Research involving genetically modified cells, viruses, or organisms other than plants...directly conflicts with section IV-3 research with genetically modified RG1 biological agents. Typically a higher containment section would override a lower one. Because the research in IV-2 would also cover research with RG1 and exception should be put under IV-3

Where does research with plasmids or replication incompetent vectors that integrate fall. Please define this explicitly.

In section IV-2 there is a defined section for clinical research involving humans. Please indicate where the same research involving animals would go.

In all areas you have the words other than plants. Where does research with plants fall?

Section IV-3: Research with well-characterized cell lines. Does this now mean that any work with any cell line will now require an IBC protocol?

Section IV-3: Research conducted with transgenic organisms at BSL-1/ABSL1. Does this now mean any work with any transgenic mice, including established mice ordered from vendors will now require IBC oversight? Also please define what is meant by transgenic mice. Do you consider all genetically modified mice as transgenic. If this is not meant to refer to modified animals, other than gene drive animals, please tell us that explicitly.

Are there no longer exemption categories as under the current NIH Guidelines?

Section IV-2: Research with primary cells that may be contaminated by adventitious agents. Please clearly define what is meant by an adventitious agent.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I agree with this.

3. Continued utility of Risk Groups: I believe this is appropriate.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I agree with this

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I think the policy is overwhelming. I believe reporting every single incident to the NIH is excessive. I understand the reporting of exposures that result in interventions, but as written, this would result in reporting of every minor occurrence and would overburden the reporter and the NIH office. You might want to dial this back a bit, and reserve if for significant events. Right now it appears that it would include reporting of incidents at BSL1 which would not cause be a risk.

6. Other feedback relevant to this resource: N/A

6. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Bioethicist

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: These are ridiculous and should be removed entirely.

6. Other feedback relevant to this resource: N/A

7. Laura Fochtmann

I am responding: On behalf of myself

Name: Laura Fochtmann

Name of Organization:

Type of Organization: Not Applicable

Role: Healthcare Provider

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: For any incidents in which there is a loss of containment of potentially infectious or hazardous agents, I would advocate that reporting also be required if there would be a significant risk to the health of animals or other wildlife in the community. For example, if an infectious agent poses a low risk to humans but release would pose a risk to birds, livestock, or pets in the community, I believe that it should be reportable. Depending on the affected animal/wildlife, there could be significant economic effects and there could also be risks of transformation and risk to human health at a later time.

6. Other feedback relevant to this resource: Although the CDC BMBL has now issued a clarification on service animals in laboratory settings, it would also be helpful to have that information explicitly stated in this document as well (https://www.cdc.gov/labs/pdf/Clarification-on-Service-Animals-Laboratories-Compliance-with-Federal-Laws-and-BMBL-Guidance.pdf)

Description: Feedback on proposed biosafety regulations

8. Sarah White

I am responding: On behalf of myself

Name: Sarah White

Name of Organization: Thermo Fisher Scientific

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 8/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Research with genetically modified organisms, viral vectors, recombinant biology, monoclonal anitbodies, research & development and biologics manufacturing

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The new policy adequately addresses gaps identified in the prior NIH Guidelines, provides more context for genetically modified organisms, wild type biological agents and allows institutional safety professionals and IBCs to focus on health-hazard-relevant research, not simply recombinant and synthetic nucleic acids.

The acronym GDMO is used 9 times in the draft but nowhere defined, gene-drive modified organism I'm assuming?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Guidance for when NIH and/or IBC approvals prior to initiation and the addition of delegated reviews will alleviate the existing intense workload of the IBC from more routine research projects, allowing focus and discussion around topics more impactful to the institution and the surrounding community.

3. Continued utility of Risk Groups: The alignment between the NIH policy and BMBL strengthen biosafety oversight and uniformly supports risk-based assessment and management of biohazards.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): As a biosafety officer who has implemented voluntary compliance at sites who manufacture viral vectors, and contract and development manufacturing facilities, the updates will streamline IBC reviews and alleviate project management pressures as IBC approval is currently a gating activity for majority of incoming work. With these changes AAV vector work will no longer be gated by IBC approval with the addition of delegated reviews.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Templates are clean and contain all pertinent information respectively.
One suggestion for the Draft Meeting Minutes Template is to reorder the rows under New IBC Registrations and Amendments for Review such that the Readout of Any Projects Approved by Delegated

Review isn't inserted between the Project Overview and Risk Assessment and Discussion; suggest to either move it to the first row in this section or after IBC Vote.

Add a separator row above New Business/Additional Topics so that these appear separate from IBCE Registrations and Amendments for Review

6. Other feedback relevant to this resource: N/A

9. Daron L. Davis

I am responding: On behalf of myself

Name: Daron L. Davis

Name of Organization: Independent Scholar

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 8/21/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Institutional governance, public accountability, multilevel governance, and governance of biomedical research oversight

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's effort to broaden biosafety oversight beyond a narrow set of research categories. My principal concern is not the scientific definition of "biohazard," on which I defer to subject-matter experts, but the institutional perimeter created by the proposed scope.

The draft appears to extend requirements beyond NIH-funded projects to non-NIH-funded biomedical research conducted at or sponsored by institutions receiving NIH funding. NIH should therefore clarify how institutional responsibility attaches when the sponsoring institution, physical research site, IBC of record, shared core facility, affiliated entity, or off-site research location are not identical.

For covered research, the policy or implementation guidance should identify the institution whose Biosafety Assurance governs the activity, the IBC of record, the institution responsible for local implementation of IBC directives, incident reporting, corrective action, public posting, and return to approved standing.

This would reduce inadvertent oversight gaps without requiring unnecessary centralization. Distribution of research activities across institutions is not inherently problematic; ambiguity about which institution retains which authority-bearing function is.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered oversight is appropriate in principle because different levels of risk do not require identical decision structures. The governance issue is whether delegation and distributed oversight remain sufficiently attributable and bounded.

NIH should provide an implementation-level authority matrix for major biosafety decisions identifying:

decision or action → authority holder → permitted delegate → scope → conditions → duration → escalation authority → corrective/override authority → required record.

This is particularly important for delegated IBC review, externally administered IBCs, and research also subject to another federal agency's oversight.

Where another federal agency has overlapping jurisdiction, NIH should specify whether that oversight supplements NIH oversight, substitutes for a defined NIH function, or governs only a particular regulatory determination. The policy should also identify which NIH responsibilities remain, including incident reporting, Biosafety Assurance oversight, corrective authority, and funding-related enforcement where applicable.

Tiering should therefore calibrate not only scientific review intensity to risk, but also the visibility of who possesses authority, who exercises it, and who can intervene when conditions change.

3. Continued utility of Risk Groups: I do not offer a substantive recommendation on the comparative scientific utility of Risk Groups versus Biosafety Levels as a baseline for biological risk assessment. That determination should be informed primarily by biosafety, microbiology, infectious-disease, and related scientific expertise.

From a governance perspective, however, whatever classification architecture NIH adopts should make clear:

1. who is authorized to make the initial classification;
2. what evidence and criteria support that classification;
3. when modification of an agent requires reassessment;
4. who may require a more protective classification or containment level;
5. how disagreements are escalated; and
6. how classification changes are recorded over the life of the protocol.

This would preserve traceability without substituting governance analysis for scientific risk judgment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary compliance through usable governance infrastructure rather than attempting to reproduce mandatory enforcement mechanisms for institutions outside the policy's formal jurisdiction.

Useful mechanisms could include standardized model Biosafety Assurance materials, voluntary IBC templates, incident-reporting tools, decision and delegation records, training resources, and technical assistance that non-NIH-funded institutions can adopt without representing themselves as formally NIH-approved where that is not the case.

NIH should also distinguish clearly between voluntary adoption of NIH practices and formal NIH oversight. Voluntary use of a template, reporting system, or biosafety standard should not create ambiguity about whether NIH possesses authority over an institution or has approved its program.

A voluntary pathway will be more credible if institutions can obtain the benefits of standardized

governance, documentation, and learning without uncertainty about the legal or institutional status created by participation.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed templates should preserve the lineage of consequential decisions while avoiding duplication of information already captured through existing NIH IBC documentation.

For IBC meeting minutes, NIH should consider adding fields for:

oversight category;
full-IBC versus delegated review;
authority for delegated review;
cross-agency authorization where applicable;
NIH determination/reference where applicable;
current protocol approval period and standing;
material modification history;
conflict-of-interest recusals and the number of unconflicted members eligible to decide the matter; and
corrective or return-to-standing actions.

For incident reports, NIH should consider fields for:

event date/time;
date/time of designated institutional awareness;
initial reporting actor and receiving office;
preliminary classification and classification authority;
subsequent changes in classification and their basis;
NIH-reportability determination;
corrective decision and responsible authority;
public-record version/date;
NIH final response where applicable; and
closure authority and current research standing.

NIH should also clarify when the proposed 24-hour reporting clock begins and whether every listed approval or compliance violation automatically triggers immediate reporting or only those meeting the policy's stated significant-risk threshold.

For public incident reporting, I recommend a two-layer record architecture: an authoritative institutional record preserving complete decision and correction lineage, and a public-facing version subject to standardized lawful redaction. Material corrections should result in visible version history rather than silent replacement.

6. Other feedback relevant to this resource: Additional implementation guidance would be particularly useful in six areas.

First, institutional scope. NIH should identify the institution of record and local implementation authority

for multi-site, affiliated, off-site, shared-core, sponsored, and externally reviewed research.

Second, externally administered IBCs. Guidance should identify who retains local implementation, inspection, incident-response, recordkeeping, emergency-action, and corrective authority when the IBC itself is external.

Third, corrective authority. NIH should publish a clear map showing who may immediately pause research, impose temporary conditions, modify or revoke delegated approval, suspend IBC approval, escalate disagreement, and authorize return to approved standing.

Fourth, conflict of interest and quorum. Where a conflicted member may count toward meeting quorum but may not participate in a specific decision, NIH should require visibility into the number of unconflicted members actually eligible to decide that protocol and consider a decision-specific unconflicted quorum.

Fifth, the National Biosafety Data and Safety Analysis Center. NIH should clarify repository access, correction, retention, versioning, institutional updates, derivative analyses, and whether NBDSAC outputs constitute technical analyses, recommendations, or merely inputs into a separate NIH decision process.

Sixth, transition. Because the policy is proposed to become effective six months after publication and will affect ongoing research, NIH should provide a transition plan addressing existing protocols, current approvals, Biosafety Assurances, external IBC arrangements, incident records, and the sequencing of any required reclassification or re-review.

These recommendations are developed through my Institutional Authority Dynamics research program, particularly Institutional Authority and Governance Dynamics (IAGD 2.3), Authority-Control Alignment, the Institutional Layer Separation Principle, Institutional Boundary Enforcement, and Authority Provenance. The application is analytical and does not constitute empirical validation of the frameworks or imply NIH adoption.

Uploaded File: Daron_L_Davis_NIH_NOT-OD-26-112_Biosafety_PUBLIC_COMMENT.pdf

Description: Full public comment: governance analysis of the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112), applying Institutional Authority Dynamics, IAGD 2.3, Authority-Control Alignment, ILSP, IBE, and Authority Provenance.

PUBLIC COMMENT ON DRAFT NIH BIOSAFETY POLICY FOR RESEARCH INVOLVING BIOHAZARDS

Notice No. NOT-OD-26-112

National Institutes of Health - Office of Science Policy

Submitted by Daron L. Davis

Independent Black Governance Researcher and Public Scholar

August 21, 2026

To the National Institutes of Health Office of Science Policy

I submit this comment on the Draft NIH Biosafety Policy for Research Involving Biohazards issued under Notice No. NOT-OD-26-112. I support NIH's objective of modernizing biosafety oversight so that it remains transparent, adaptive, accountable, and calibrated to risk. The draft policy substantially strengthens institutional governance by expanding coverage to a broader range of biohazards, establishing tiered oversight, requiring NIH-approved Biosafety Assurances, strengthening Institutional Biosafety Committees (IBCs), formalizing incident reporting, and expanding public transparency.

My recommendations focus on a narrower governance question: as biosafety oversight becomes more distributed across NIH, institutions, IBCs, delegated reviewers, Biological Safety Officers (BSOs), Principal Investigators (PIs), externally administered IBCs, and other federal agencies, how can the policy preserve clear authority, authorization, accountability, provenance, institutional boundaries, and corrective control?

Research basis and analytical approach

I submit this comment as an independent Black governance researcher and public scholar developing the Institutional Authority Dynamics research program, an integrated political-science research enterprise examining how institutional authority is formed, exercised, distributed, governed, preserved, defended, and made accountable across complex governance systems.

This submission applies a bounded set of components from that research architecture:

- Institutional Authority and Governance Dynamics (IAGD 2.3) - the integrating theoretical architecture. IAGD treats Authority-Control Alignment as the central hinge between formally constituted Institutional Authority and practical Governance Control.
- Authority-Control Alignment - assessed across four dimensions: Locational (authority and control reside where intended); Authorization (actor, action, scope, conditions, and period are authorized); Accountability (actors answer for Authority Exercise); and Corrective (institutions detect, intervene, and correct).
- Institutional Layer Separation Principle (ILSP) - differentiates Governance, Authority, Execution, and Infrastructure so authority-bearing functions remain distinguishable and data movement remains traceable.
- Institutional Boundary Enforcement (IBE) - maintains jurisdictional, procedural, functional, and accountability boundaries and guards against persistent boundary failure.
- Authority Provenance - the cross-cutting evidentiary layer tracing consequential claims, decision rights, delegations, Authority Exercise, and Governance Control arrangements to their source, recognition, authorization, transformations, retained rights, and present standing.

This is a bounded public-policy application of the research program. It does not constitute empirical validation of these frameworks, determine whether a particular biosafety decision is scientifically or legally correct, or imply adoption of the research by NIH.

Executive summary of recommendations

1. Define the institutional perimeter of responsibility for research that is conducted at or sponsored by an NIH-funded institution, especially for affiliated entities, shared cores, off-site work, multi-site research, and externally administered IBCs.
2. Clarify when oversight by another federal agency supplements, substitutes for, or controls only a defined function of NIH oversight, and identify which NIH responsibilities remain.
3. Carry forward and make explicit the authority and accountability controls for delegated review and externally administered IBCs, including local implementation and override responsibility.
4. Strengthen decision integrity where conflicted IBC members may count toward quorum by requiring a decision-specific record of unconflicted voting capacity.
5. Clarify incident-reporting triggers, the point at which the 24-hour clock begins, the distinction between preliminary and final classifications, and the governance of public incident records.
6. Use the incident-reporting and IBC-minute templates to preserve policy-specific provenance rather than duplicating information already captured in NIH's existing meeting-minute guidance.
7. Make corrective authority and return-to-approved-standing as explicit as initial approval authority.
8. Define governance, access, correction, versioning, and analytical-status controls for the National Biosafety Data and Safety Analysis Center (NBDSAC).
9. Provide a transition architecture for existing protocols, Biosafety Assurances, externally administered IBC arrangements, and current approvals during the six-month implementation period.

I. Define the institutional perimeter and cross-agency authority configuration

A. Clarify the institutional perimeter of responsibility

The draft policy applies not only to NIH-supported research, but also to non-NIH-funded biomedical research conducted at an institution that receives any NIH funding. It further provides that, as a term and condition of NIH funding, institutions shall ensure that research conducted at or sponsored by the institution, irrespective of funding source, complies with the policy.

This expansion creates an important institutional-boundary question. The final policy or implementation guidance should define how responsibility attaches when research is conducted through affiliated entities, shared core facilities, off-site laboratories, multi-site studies, clinical locations, or other arrangements in which the sponsoring institution, physical research site, and local oversight body are not identical.

I recommend that NIH require an identifiable responsibility record for covered research that states, as applicable:

- the institution whose Biosafety Assurance governs the activity;
- the physical site where research is conducted;
- the IBC of record;
- the institution responsible for local implementation of IBC directives;
- the responsible BSO or other designated official;
- the institution responsible for incident reporting and public posting;
- the institution with immediate corrective authority; and
- the institution responsible for confirming return to approved standing.

This is principally an IBE and Locational Alignment issue. Distribution across institutions is not inherently problematic; ambiguity about which institution retains which authority-bearing function is.

B. Clarify overlapping federal oversight

The draft states that covered research also under the regulation or purview of another federal agency may proceed under the oversight of that agency once applicable approvals or clearances have been obtained. This provision should be clarified because 'under the oversight of the other federal agency' may describe several materially different relationships.

The final policy should specify whether another federal agency's oversight:

- supplements NIH oversight;
- substitutes for a defined NIH review function;
- controls only a specific regulatory determination;
- changes institutional incident-reporting obligations;
- changes containment or corrective authority; or
- leaves NIH funding, Assurance, and enforcement authority intact while another agency governs the underlying research activity.

Whenever overlapping federal jurisdiction applies, the record should identify the operative authority configuration: NIH authority, other federal authority, institutional authority, the affected decision right, continuing NIH responsibilities, reporting pathways, and corrective authority.

II. Govern delegated review and externally administered IBCs as distinct authority arrangements

A. Delegated review

The draft permits lower-risk research and minor amendments to be reviewed and approved by an individual or subgroup of IBC members. Delegated reviewers may elevate matters to the full IBC, and all delegated approvals must be reported in full to the IBC at its next scheduled meeting.

This is a reasonable streamlining mechanism, but the record should preserve the difference between authority exercised by the full IBC and authority exercised under delegation.

For delegated review, NIH should require or recommend documentation of:

- the provision authorizing delegated review;
- the reviewer or subgroup exercising delegated authority;
- the research category or amendment qualifying for delegation;
- the decision and conditions of approval;
- the period of authorization;
- mandatory escalation criteria;
- whether escalation was considered or required;
- the date the full IBC was notified; and
- the later full-IBC action, if any, affecting the delegated determination.

B. Externally administered IBCs

The proposed Biosafety Assurance asks institutions to disclose whether they use an externally administered IBC. Existing NIH guidance already establishes useful controls for such arrangements: the research-performing institution registers the IBC, the external IBC must possess appropriate local expertise and knowledge, and an individual at the research-performing institution must have authority and responsibility to implement the IBC's directives.

The final policy should expressly preserve or incorporate those safeguards so the modernization effort does not inadvertently make external review less governable than current practice.

For externally administered IBCs, the final implementation materials should identify:

- which institution is the IBC of record;
- who possesses local implementation authority;
- how local facility, training, and operating information reaches the external IBC;
- who performs local inspections and periodic compliance review;
- who receives and investigates incidents;
- who may impose an immediate local pause or additional biosafety condition;
- who maintains authoritative records and public postings; and
- how disagreements between the external IBC and the research-performing institution are resolved.

ILSP is especially useful here: review, local execution, institutional responsibility, and technical infrastructure may be distributed while remaining distinguishable.

III. Strengthen decision integrity where conflict-of-interest recusals interact with quorum

The draft appropriately prohibits an IBC member from reviewing or approving a project in which the member is engaged or expects to be engaged, or in which the member has a direct financial or other conflict of interest. The draft also provides that a recused member may nevertheless be counted toward the voting quorum for the meeting.

That design can create a decision-specific governance problem: a meeting may satisfy the formal meeting quorum while the number of unconflicted members eligible to decide a particular protocol is smaller.

I recommend that NIH require the meeting record to identify, for each affected decision, the recused member, the basis for nonparticipation at an appropriate level of detail, the number of voting members eligible to participate in that decision, and whether the decision-specific eligible membership satisfied the required voting threshold.

NIH could go further and require an unconflicted decision-specific quorum. At minimum, the record should make visible whether formal meeting quorum and actual decision capacity diverged.

This recommendation builds on NIH's existing 2025 IBC meeting-minute guidance, which already calls for documentation of quorum, member attendance, voting results, conflicts, protocol identifiers, risk assessments, conditions of approval, and verification of conditions. The new policy-specific template should extend that record rather than duplicate it.

IV. Clarify incident classification, reporting triggers, public records, and templates

A. Clarify the 24-hour reporting trigger and institutional awareness

The draft requires immediate NIH notification, within 24 hours or as soon as the institution becomes aware, for incidents posing a significant risk to human health. The listed reportable events include confirmed or potential laboratory-acquired infections, certain releases, high-containment incidents, specified BSL-2 exposures, and any compliance violations at any BSL/ABSL such as failure to obtain or maintain required IBC or NIH approval.

The final policy should clarify two points. First, NIH should state whether every listed compliance violation is automatically subject to the immediate reporting requirement or whether the violation must also satisfy the stated significant-risk threshold. Second, NIH should define when the 24-hour clock begins.

For example, 'institution becomes aware' could mean awareness by the PI, BSO, IBC Chair, AOR, institutional biosafety office, or another designated official. A defined institutional-receipt trigger would support consistent reporting and avoid incentives to argue over which individual's knowledge starts the clock.

B. Preserve classification lineage

The incident record should distinguish an event from the institutional and federal classifications later assigned to it. A useful lineage is:

event -> initial notification -> preliminary classification -> investigation -> verified facts -> institutional determination -> NIH-reportability determination -> corrective action -> final report -> NIH response -> closure

The template should separately identify incident, near miss, anomaly, suspected exposure, confirmed exposure, policy violation, preliminary information, verified fact, institutional determination, NIH determination, and final disposition where those distinctions apply.

C. Use a two-layer public-record architecture

The draft requires all incident reports to be posted on an institutional public-facing webpage, with final reports posted within 30 days of NIH's final response for NIH-reportable incidents or within 30 days of institutional

finalization for incidents not reportable to NIH. NIH's final response must be posted with NIH-reportable incidents. IBC meeting minutes and incident reports must remain publicly posted for at least five years.

I support the transparency objective. The final implementation design should distinguish the authoritative institutional record from the public-facing record.

I recommend a two-layer approach:

- Authoritative record - preserves complete provenance, internal correction history, decision lineage, and any information lawfully maintained by the institution.
- Public-facing record - contains the required incident or meeting information after standardized redaction for privacy, proprietary interests, national security, or other permissible protections.

When the authoritative record is materially corrected, the public version should be updated with a visible correction or version history rather than silently replaced. This preserves transparency while avoiding the inference that every initially reported fact remained unchanged after investigation.

D. Add new-policy fields to the required templates

NIH specifically requests comment on incident-reporting and IBC meeting-minute templates. Existing NIH meeting-minute guidance already captures substantial decision provenance. The modernization templates should therefore add only what the new policy's architecture requires.

For IBC meeting minutes, NIH should consider adding fields for:

- oversight category under Section IV;
- full-IBC versus delegated review;
- delegated-review authority and reviewer identity or role;
- cross-agency authorization or clearance where applicable;
- NIH determination or reference where applicable;
- current protocol approval period and standing;
- material modification lineage;
- decision-specific conflict recusals and eligible voting capacity; and
- corrective or return-to-standing action when a prior approval has been paused or modified.

For incident reports, NIH should consider adding fields for:

- date and time of event;
- date and time of designated institutional awareness;
- initial reporting actor and receiving institutional office;
- preliminary incident classification and classification authority;
- changes in classification and the basis for change;
- NIH-reportability determination;
- corrective decision and responsible authority;
- public-record version/date;
- NIH final response, when applicable; and
- closure authority and current research standing.

V. Make corrective authority and return to approved standing as explicit as initial approval authority

The draft already assigns meaningful corrective responsibilities. The BSO investigates incidents and reports significant problems; the IBC reviews incidents and determines whether additional biosafety measures are warranted; NIH reviews reportable incidents, verifies institutional responses, and may require additional action; and NIH may restrict or withdraw Biosafety Assurances.

The remaining gap is narrower: the policy is less explicit about the immediate and intermediate authority sequence when previously approved research must be paused, modified, or restored.

Implementation guidance should identify, by research category:

- who may order an immediate pause;
- who may impose temporary containment or procedural conditions;
- who may modify or revoke a delegated approval;
- who may suspend or modify an IBC approval;
- what emergency authority a BSO or designated official possesses;
- when NIH involvement becomes mandatory;
- how disagreement among the PI, BSO, IBC, institution, and NIH is escalated;
- what record is required for emergency action; and
- who authorizes return to approved standing after correction.

The governing principle is that the institution authorized to approve research should not be easier to identify than the institution authorized to stop, modify, or restore it.

VI. Define governance and provenance controls for the NBDSAC

The draft establishes the National Biosafety Data and Safety Analysis Center as an FFRDC that independently aggregates, de-identifies, and analyzes laboratory biosafety incident data, near misses, and anomalies. Institutions are encouraged to submit voluntary confidential reports, and NIH states that voluntarily submitted data will not be used for enforcement or funding action where the incident did not result in an environmental release or laboratory-acquired infection.

This is a promising learning architecture. The final policy or implementation materials should nevertheless distinguish technical analysis from NIH Authority Exercise and define Governance Control over the repository.

NIH should clarify:

- which entity governs repository access and access authorization;
- retention periods for raw, transformed, and derivative datasets;
- how institutions correct, supplement, or update submitted records;
- whether and how institutions may withdraw voluntary submissions;
- how de-identified records preserve version lineage without exposing institutional or individual identities;
- how derivative analyses identify the data version or corpus used;
- what review applies before analytical findings are published or used in policy development; and
- whether NBDSAC outputs are technical analyses, recommendations, or inputs to a separate NIH decision process.

The last distinction is important because expertise, technical custody, or analytical control do not by themselves establish Institutional Authority. Authority Provenance should preserve the path from NBDSAC analysis to any later NIH policy or enforcement decision without treating the FFRDC's analytical role as equivalent to NIH decision authority.

VII. Provide an explicit transition architecture for existing research and institutional arrangements

NIH proposes that the final policy become effective six months after publication and apply to existing awards and agreements, ongoing intramural research, and non-NIH-funded biomedical research at institutions receiving NIH funding. Biosafety Assurances may be approved for up to four years, while protocol approvals may extend for up to three years.

A six-month transition can succeed only if institutions know which existing approvals remain valid and which must be reclassified, re-reviewed, or incorporated into a new Biosafety Assurance.

NIH should provide implementation guidance addressing:

- whether currently approved protocols remain valid through their existing approval periods;
- which ongoing activities require reclassification under the new Section IV tiers;
- whether existing IBC registrations convert into or inform the new Biosafety Assurance;
- deadlines and sequencing for initial Biosafety Assurance approval;
- how existing externally administered IBC arrangements transition;

- treatment of pending amendments and new protocols during the transition period;
- how current incident records and public-posting obligations migrate into the new system; and
- a staged implementation option if full immediate re-review would create an avoidable institutional backlog.

This directly addresses NIH's request for feedback on administrative burden and implementation resources. A transparent transition architecture can preserve accountability without forcing institutions to reconstruct every governance relationship at once.

VIII. Preserve and build upon the draft policy's existing governance strengths

The draft already contains substantial governance infrastructure that should be retained. It requires institutional lines of authority, NIH-approved Biosafety Assurances, independent IBC risk assessment, periodic review, conflict-of-interest restrictions, unaffiliated community membership, incident review and reporting, public minutes, public incident reports, defined NIH review for specified higher-risk activities, and reporting of delegated approvals to the full IBC.

Existing NIH guidance for externally administered IBCs and IBC meeting minutes also provides useful controls that should be carried forward rather than displaced. My recommendations are intended to connect these existing and proposed safeguards into a clearer authority, provenance, boundary, and corrective-control architecture.

Consolidated recommendations

1. Define the institution of record and local implementation authority when covered research crosses institutional, geographic, sponsorship, or oversight boundaries.
2. Clarify whether other federal-agency oversight supplements, substitutes for, or controls only a defined function of NIH oversight.
3. Document delegated-review authority, scope, escalation, duration, and full-IBC reporting.
4. Expressly preserve current safeguards for externally administered IBCs, including local knowledge and local implementation authority.
5. Require decision-specific visibility into conflict recusals and unconflicted voting capacity; consider a decision-specific unconflicted quorum.
6. Clarify whether all listed compliance violations trigger 24-hour reporting and define the event that constitutes institutional awareness.
7. Preserve incident classification lineage from initial report through final disposition.
8. Use an authoritative-record/public-record model with visible correction and version history.
9. Add policy-specific provenance fields to the incident-reporting and IBC-minute templates rather than duplicating existing minute requirements.
10. Publish a corrective-authority map for pause, modification, override, emergency action, escalation, and return to approved standing.
11. Define NBDSAC repository governance, correction, versioning, access, and the institutional status of its analytical outputs.
12. Publish a transition plan for existing protocols, Biosafety Assurances, external IBCs, incident records, and ongoing research during the six-month implementation period.

Conclusion

The draft NIH Biosafety Policy recognizes that modern biomedical research requires a more distributed and adaptive oversight system. Distributed governance can improve expertise, responsiveness, risk calibration, and institutional learning. It also increases the importance of knowing where authority resides, who is authorized to exercise it, how consequential decisions move across institutional layers, who remains accountable, and who possesses corrective control when conditions change.

A durable governance principle follows: oversight should not distribute Authority Exercise faster than institutions can preserve its location, authorization, accountability, provenance, boundaries, and corrective control.

The draft already contains much of the infrastructure necessary to meet that standard. Clearer institutional perimeters, cross-agency rules, delegation records, decision-integrity controls, incident provenance, corrective pathways, NBDSAC governance, and transition guidance would strengthen the architecture without requiring unnecessary centralization.

Respectfully submitted,

Daron L. Davis

Independent Black Governance Researcher and Public Scholar

References

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2. National Institutes of Health, Office of Science Policy. Draft NIH Biosafety Policy for Research Involving Biohazards (2026).
3. National Institutes of Health, Office of Science Policy. NIH Guidance: Institutional Biosafety Committee Meeting Minutes Template and Points to Consider (June 2025).
4. National Institutes of Health, Office of Science Policy. FAQs on Externally Administered IBCs (current NIH guidance).
5. National Institutes of Health, Office of Science Policy. Incident Reporting FAQs (December 2023; current OSP guidance page).
6. Davis, Daron L. Institutional Authority and Governance Dynamics (IAGD 2.3): Construct Boundary and Visual Semantics Harmonization. 2026. DOI: 10.5281/zenodo.21987181.
7. Davis, Daron L. IAGD Conceptual Vocabulary and Construct Boundaries: Public Edition v1.2. 2026. DOI: 10.5281/zenodo.21385641.
8. Davis, Daron L. Institutional Layer Separation in GovTech: Preserving Public Accountability Under Distributed Digital Execution. 2026. DOI: 10.5281/zenodo.20784348.
9. Davis, Daron L. Institutional Boundary Enforcement: A Theory of Authority Preservation under Distributed Administrative Execution. 2026.

Submission information

NIH response deadline: October 19, 2026.

Submission method: NIH Office of Science Policy electronic comment form.

Notice: NOT-OD-26-112.

NIH states that responses may be posted publicly without redaction after OSP review. The submission should therefore contain no proprietary, classified, confidential, sensitive, or unnecessary personally identifiable information.

10. Thomas E. Martin III

I am responding: On behalf of myself

Name: Thomas E. Martin III

Name of Organization: Elite Supply & Services, LLC - reessdata.com

Type of Organization: Professional Organization/Association

Role: Investigator/Researcher

Date Submitted: 8/21/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): reessdata.com

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Baseline commissioning and periodic verification of required ventilation and containment controls using calibrated equipment.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Documentation of applicable fresh air airflow, pressure relationships, exhaust pathways, HEPA-filter integrity, alarm performance, maintenance, deficiencies, and corrective actions.

3. Continued utility of Risk Groups: Incident and near-miss reporting that captures ventilation failures, abnormal pressure or airflow, equipment failures, potential exposures, reported symptoms, and medical responses.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Occupational-health and disability planning for workers, patients, and research participants with asthma, reduced respiratory function, or other health vulnerabilities.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public summaries identifying when engineering controls were verified, what deficiencies were found, and whether corrective actions were completed—while protecting security and personal information.

6. Other feedback relevant to this resource: Patient symptoms alone do not establish causation, and consumer monitors do not certify laboratory performance. However, reported symptoms, sensor anomalies, equipment alarms, and repeatable patterns should trigger a qualified investigation rather than dismissal.

Establish the baseline. Verify the controls. Document incidents and outcomes. You cannot manage what you do not monitor.

Description: Email Submission from tom.elitesupply@gmail.com

11. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Biosafety Specialist

Date Submitted: 8/21/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The guidance states that “IBC approval is required to lower the containment of wild-type or genetically modified RG3 or RG4 biological agents that NIH has previously approved to be conducted at lower containment.” It would be helpful for NIH to provide additional guidance or a publicly available list identifying the wild-type or genetically modified RG3/RG4 agents that have previously been approved for work at lower containment levels. It is currently unclear how institutions are expected to determine whether a particular agent has received such prior NIH approval. Additionally, clarification would be helpful regarding whether these approvals are specific to individual projects or institutions (e.g., NIH-funded research) or whether a prior NIH approval may be applied more broadly when an IBC evaluates similar work.

12. Tyler Kelly

I am responding: On behalf of myself

Name: Tyler Kelly

Name of Organization: Lazarus 3D

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Investigator/Researcher

Date Submitted: 8/21/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The inclusion of the non-specific term "toxins" is problematic as defined. The proposed rules define "toxins" as "A protein or peptide produced by living organisms that causes harm in humans." This definition effectively turns any work with any cell - regardless of lack of genetic alterations - into a "biohazard" as virtually any cell produces proteins that can cause harm in humans. For example, many types of cells produce classes of proteins known as cytokines. While these are normally signaling proteins, they in humans they can become elevated to the point of becoming a medical emergency - "cytokine storm" - thus demonstrating harm. As such, even someone doing simple work culturing very basic endothelial cells is engaged in "biohazardous" work due to the ability of those cells to produce a protein - any of a number of cytokines - that has the potential to cause harm. This illustrates why the definitions proposed are vague, unworkable, and require revision.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

13. Jeffrey Peters

I am responding: On behalf of myself

Name: Jeffrey Peters

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 8/23/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer, general research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Perspective of Respondent
I am a biomedical scientist with extensive experience conducting cancer research using established human cancer cell lines, genetically modified cells, and animal xenograft models. I also served as a member of an Institutional Biosafety Committee for approximately 20 years, including many years as Chair. These comments therefore reflect experience both as an investigator conducting laboratory research and in the institutional oversight and risk assessment of such research. These comments are submitted in my individual capacity and are not submitted on behalf of my institution.
Clarify whether well-characterized human cell lines are actually within the scope of the Policy

There appears to be an important ambiguity between Section II and Section IV-3.

Section II defines covered biohazards as disease-causing biological agents, genetically modified cells or organisms, toxins/prions, or cells or organisms containing such hazards. A well-characterized, unmodified human cancer cell line without an identified infectious agent does not clearly meet this definition.

Nevertheless, Section IV-3 specifically identifies “research with well-characterized cell lines” as research requiring delegated review and approval.
NIH should clarify whether all established human cell lines are intended to fall within the Policy, or only those that otherwise meet the definition of a covered biohazard.

Established cancer cell lines are used in a large fraction of routine biomedical research. Ambiguous language could result in institutions interpreting essentially all human cell-culture research as subject to IBC oversight, even when no infectious agent or other defined biohazard is present.

There is also a scientifically important difference between primary human material that may contain unknown adventitious agents, established cell lines with incomplete characterization, and authenticated, well-characterized cell lines with no known infectious hazard. The draft already recognizes this

distinction by placing primary cells potentially contaminated by adventitious agents into a higher category of review than well-characterized cell lines. NIH should make the implications of that distinction explicit.

Suggested NIH clarification:
Well-characterized, established human or animal cell lines that have not been genetically modified, do not contain a known or reasonably suspected infectious biological agent or other biohazard covered by this Policy, and do not otherwise meet the definition of research involving biohazards are outside the scope of the Policy.
For cell lines that are within the Policy solely because they have been genetically modified, the risk assessment should focus on the biological consequences of the modification rather than treating genetic modification itself as evidence of increased hazard.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Clarify the treatment of BSL-1 and other very-low-risk research

The draft appropriately excludes research involving wild-type RG1 biological agents from the Policy. However, genetically modified RG1 agents, transgenic organisms at BSL-1/ABSL-1, and other low-risk materials remain subject to prior review and approval, albeit through delegated review.

This creates the potential for very-low-risk research to receive controls that are not clearly proportional to the hazard identified in the protocol-specific risk assessment.

The stated goal of the revised Policy is to expand appropriate biosafety oversight while reducing unnecessary administrative burden for low-risk research. For this objective to be realized, institutions need clearer direction that BSL-1 and equivalent low-risk research should not automatically acquire BSL-2 practices or additional engineering controls simply because it technically falls within the scope of the Policy. Risk mitigation should be proportional to the identified hazard, not simply to the fact that genetic modification has occurred.

Suggested NIH clarification:

For research involving RG1 agents, BSL-1/ABSL-1 transgenic organisms, and other low-risk biological materials, additional containment practices or engineering controls beyond those appropriate to BSL-1/ABSL-1 should be required only when the protocol-specific risk assessment identifies a scientifically plausible hazard and exposure pathway that warrants those additional controls.

NIH should also encourage institutions to establish standardized or expedited delegated-review procedures for recurring categories of low-risk research rather than requiring protocol-by-protocol reconsideration of well-established activities.

More generally, additional containment requirements should be proportional to risk and supported by an identified biohazard, a scientifically plausible route of exposure, and an assessment of both the likelihood and potential consequence of that exposure.

Local IBC discretion remains important because facilities, personnel, and experimental circumstances differ. However, local discretion should operate within an evidence-based framework established by NIH so that low-risk research is not subjected to substantially different containment requirements among institutions based primarily on theoretical rather than reasonably supported hazards.

3. Continued utility of Risk Groups: RG and BSL should both remain useful components of risk assessment, but they should not be treated as interchangeable.

RG primarily characterizes the inherent hazard associated with a biological agent, whereas BSL describes a combination of containment practices, safety equipment, and facility requirements appropriate to particular work. The appropriate containment for an experiment should therefore be determined through protocol-specific risk assessment that considers both the biological properties of the material and the manipulations being performed.

Assignment of a material or experiment to BSL-2 should not automatically imply that every manipulation requires every available BSL-2 engineering control. Conversely, a particular manipulation may warrant additional controls when it creates a credible exposure pathway.

NIH should preserve this distinction explicitly in the final Policy and implementation guidance. For genetically modified agents, the starting RG of the parent agent remains useful, but the actual effects of the modification on pathogenicity, replication, host range, transmissibility, and other relevant properties should determine whether the risk has increased, decreased, or remained unchanged. Genetic modification itself should not be treated as evidence that risk has increased.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comment. My comments are focused on NIH-supported and institutionally overseen research, risk-proportionate oversight, and implementation guidance for low-risk biomedical research.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: No comment at this time.

6. Other feedback relevant to this resource: I strongly recommend that NIH implementation resources provide additional guidance in the following four areas. Based on my experience both conducting biomedical research and serving for approximately 20 years on an IBC, including many years as Chair, these are areas in which lack of clear guidance can result in substantial variation among institutions and precautions that may not be proportional to the identified risk.

1. Routine xenograft research with established human cancer cell lines

Routine implantation or injection of established human cancer cells into laboratory mice is common in cancer research. Institutional requirements for these experiments can vary, including requirements for biosafety-cabinet use based on the possibility of an unrecognized infectious agent even when no agent has been identified. Clear NIH guidance would help ensure that such requirements are tied to protocol-specific evidence and plausible exposure pathways.

There are legitimate hazards associated with these procedures, particularly the use of sharps and the possibility of accidental inoculation of viable cells. Those risks should be addressed. However, the hazard presented by accidental percutaneous inoculation is fundamentally different from an inhalational infectious hazard. A risk assessment should distinguish among accidental needle-stick or self-inoculation, splash or mucosal exposure, adventitious infectious-agent exposure, and aerosol-mediated exposure.

The fact that human tumor cells can form a tumor in an immunodeficient mouse does not, by itself, demonstrate that those cells constitute an aerosol-transmissible infectious hazard to laboratory personnel.

Suggested NIH clarification:

For animal studies involving well-characterized human cell lines, containment and procedural requirements should be based on identified or reasonably supported hazards associated with the cell line and the experimental procedure. The ability of a cell line to form a tumor in an experimental animal should not, by itself, be considered evidence of an infectious or aerosol-transmissible hazard.

When the primary identified hazard is accidental inoculation of viable cells through the use of sharps, risk mitigation should primarily address that exposure pathway. Additional containment measures intended to prevent inhalational exposure should be required only when an inhalational hazard has been identified through the protocol-specific risk assessment.

2. Clarify when use of a biosafety cabinet is actually required

Section V-E identifies biosafety cabinets as one possible form of primary containment but does not establish criteria for determining when a biosafety cabinet is necessary. Without additional guidance, BSL-2 designation could be interpreted as supporting routine BSC use even for manipulations in which the protocol-specific assessment has not identified a meaningful exposure pathway that the BSC is intended to mitigate.

A biosafety cabinet is an engineering control. Like any engineering control, its use should correspond to an identified hazard. BSL designation should not be interpreted to mean that every manipulation associated with that BSL must necessarily be performed within a BSC.

For example, a procedure involving a needle and syringe may primarily present a percutaneous inoculation hazard. Conducting the procedure inside a BSC does not eliminate the sharps hazard and may not materially reduce the primary risk. Conversely, manipulations of infectious material that generate respirable aerosols may clearly warrant primary containment.

Suggested NIH clarification:

Assignment of BSL-2 or ABSL-2 containment does not, by itself, require that every manipulation be performed within a biosafety cabinet. The requirement for use of a biosafety cabinet or other primary containment device should be based on the specific agent, procedure, quantity, route of exposure, and

likelihood and consequence of exposure identified in the protocol-specific risk assessment.

When an IBC requires an engineering control beyond standard practices for the assigned containment level, the risk assessment should identify the specific hazard and credible exposure pathway addressed by that control.

3. Define aerosol generation in terms of biological risk rather than merely physical aerosol production

Section V-D appropriately identifies generation of aerosols as a factor that can modify risk. However, the term “generation of aerosols” is sufficiently broad that almost any manipulation of liquid biological material could theoretically be described as aerosol generating.

Aerosol risk depends upon more than whether microscopic droplets can theoretically be produced. A meaningful aerosol hazard requires consideration of whether the material in the aerosol can cause harm; whether the procedure produces particles capable of reaching an appropriate route of exposure; whether the material remains viable or biologically active; the quantity or concentration potentially generated; the infectious or harmful dose, where known; and whether inhalation or mucosal deposition is a biologically plausible route of exposure.

Without this distinction, the theoretical ability to create droplets during pipetting, injection, animal inoculation, or other commonplace procedures could become sufficient justification for additional containment even where no inhalational hazard has been demonstrated.

Suggested NIH clarification:

An aerosol-generating procedure is a manipulation that can reasonably be expected to generate droplets or particles containing a biological material in a form, quantity, and particle size capable of producing a biologically meaningful exposure through inhalation or mucosal deposition.

The theoretical physical generation of droplets or aerosol particles should not, by itself, constitute an aerosol hazard requiring additional containment. The risk assessment should consider whether the biological material presents a credible hazard through the relevant route of exposure.

4. Ensure appropriate clinical expertise is available when assessing potential human-health consequences

The proposed Policy requires IBCs to assess both the likelihood of exposure to a biohazard and the potential severity of resulting harm to research personnel. However, the proposed IBC membership requirements do not specifically require clinical or occupational-health expertise when the committee is evaluating the medical consequences of a potential exposure or developing exposure-response requirements.

Biosafety professionals have essential expertise in containment, laboratory practices, and exposure prevention. However, determining whether a particular exposure is likely to result in infection, disease,

or other clinically meaningful harm may require different expertise. This distinction is particularly important when a risk assessment involves the clinical significance of inhalation, mucosal exposure, accidental inoculation, adventitious agents, susceptibility to infection, or the appropriate medical response following an exposure.

The need is not necessarily for a physician to serve on every IBC or participate in every review. Rather, the committee should obtain relevant clinical expertise when its safety determination depends materially on a medical judgment.

Suggested NIH clarification:

When an IBC risk assessment depends materially upon the predicted human-health consequences of a potential exposure, the IBC should include or obtain consultation from an individual with appropriate clinical or occupational-health expertise relevant to the potential exposure. Such expertise may be provided by an appropriately qualified physician, occupational-health clinician, infectious-disease specialist, or other qualified healthcare professional, as appropriate to the specific risk being evaluated.

Clinical consultation should be considered particularly when the severity of a hypothetical health consequence is being used to justify additional containment, engineering controls, personal protective equipment, or restrictions on otherwise low-risk research.

Overall recommendation

The proposed Policy appropriately moves toward protocol-specific, risk-based oversight and recognizes that Risk Group and Biosafety Level are related but distinct concepts. To achieve the stated objective of reducing unnecessary burden for low-risk research, NIH should provide stronger safeguards against equating theoretical possibility with meaningful biological risk.

Additional containment requirements should be proportional to risk and supported by an identified biohazard, a scientifically plausible route of exposure, and an assessment of both the likelihood and potential consequence of that exposure.

IBC discretion remains important because local facilities, personnel, procedures, and circumstances differ. However, local discretion should operate within an evidence-based risk-assessment framework. A requirement for additional containment should identify the hazard being mitigated and explain how the required intervention materially reduces that risk. Risk assessments that depend on predicted medical consequences should also incorporate appropriate clinical or occupational-health expertise.

14. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 8/23/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biochemistry

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's goal of expanding the biosafety framework beyond recombinant and synthetic nucleic acid research and establishing a more comprehensive, risk-based policy. However, the proposed scope is extremely broad and should be more clearly calibrated to actual biosafety risk.

In particular, the definition of genetic modification would bring a very large amount of routine molecular and cell biology under the policy, including many experiments involving established mammalian cell lines, plasmid transfection, reporter constructs, CRISPR-modified cells, and other low-risk activities. The policy appropriately recognizes some of these activities as lower risk, but they nevertheless remain formally subject to oversight.

I recommend that NIH distinguish more clearly between research that presents a meaningful biosafety hazard and routine laboratory manipulation that is technically a genetic modification but does not materially increase risk. NIH should consider a categorical exemption or registration-only pathway for well-characterized low-risk activities, such as routine plasmid transfection of established mammalian cell lines, non-replicating reporter constructs, and comparable BSL-1 activities.

I am also concerned about the provision extending the policy to non-NIH-funded research conducted at institutions that receive NIH funding. As written, NIH requirements would effectively become the institutional biosafety framework for covered research regardless of funding source. This may be reasonable for research involving substantial biohazards, but NIH should consider providing institutions greater flexibility for unrelated, low-risk, non-NIH-funded work.

The overall principle should be that scope follows meaningful biosafety risk, rather than simply whether an experiment meets a broad technical definition of genetic modification.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I strongly support the concept of tiered oversight. Federal review should be reserved for research involving substantial uncertainty or potentially significant consequences, while institutions and IBCs should retain

responsibility for routine risk assessment and local oversight.

The proposed distinction among research requiring NIH and IBC approval, full IBC review, and delegated IBC review is a useful framework. However, the lowest-risk tier should be made substantially more streamlined.

For example, the draft places well-characterized cell lines, plasmids, replication-incompetent non-integrating viral vectors expressing low-risk transgenes, and certain other low-risk work into a delegated-review pathway. Although preferable to full committee review, delegated review still requires submission, review, documentation, tracking, and renewal. At institutions conducting large amounts of molecular and cell biology, this could result in substantial administrative workload without a corresponding increase in biosafety.

I recommend adding an additional category for activities that require only institutional registration or notification, rather than formal approval. Such a pathway could include clearly defined routine BSL-1 and low-risk BSL-2 activities.

Federal review should remain focused on research involving novel, emerging, zoonotic, RG3/RG4, gene-drive, or otherwise uncertain hazards where national consistency and specialized expertise are necessary. Local IBCs are better positioned to evaluate routine work because they understand the facilities, personnel, training, and institutional context.

Tiering will be successful only if each tier represents a meaningful difference in administrative burden as well as a difference in risk.

3. Continued utility of Risk Groups: Risk Groups remain useful as a starting point for characterizing the inherent properties of a biological agent, but they should not be treated as equivalent to Biosafety Levels or used by themselves to determine containment.

I strongly support the draft policy's recognition that RG and BSL are related but distinct concepts. RG classification reflects properties of the agent, while appropriate BSL depends on the actual experiment, including genetic modifications, volume, aerosol generation, use of sharps, routes of exposure, animal procedures, and other manipulations.
This distinction becomes particularly important for genetically modified agents. A modification may increase risk by changing host range, transmissibility, pathogenicity, stability, or other biological properties, but it may also reduce risk through attenuation or replication deficiency. Therefore, neither the parent-agent RG nor a fixed BSL assignment should substitute for experiment-specific risk assessment.

I recommend retaining RGs as a baseline descriptor while using BSL/ABSL as the outcome of a comprehensive risk assessment. NIH should provide clear examples illustrating situations in which genetic modification or experimental manipulation appropriately raises or lowers containment relative to the baseline RG.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary adoption by making the policy practical, scalable, and clearly proportional to risk rather than by attempting to reproduce the full administrative structure required of NIH-funded institutions.

The most effective mechanism would be a set of freely available model resources that institutions can adopt in whole or in part. These could include standardized risk-assessment tools, model biosafety procedures, training materials, incident-reporting guidance, template IBC procedures, and simplified pathways for low-risk research.

A tiered voluntary framework would be especially useful for smaller institutions that may not have extensive biosafety infrastructure. For example, NIH could provide a basic framework for institutions conducting only BSL-1 and BSL-2 work and a more extensive framework for institutions conducting higher-risk research.

NIH should also promote access to regional or external biosafety expertise for institutions that do not maintain a full internal biosafety program.

Voluntary compliance will be more successful if institutions perceive the policy as a useful safety framework rather than as an administratively burdensome compliance system. NIH should therefore emphasize technical assistance, model resources, training, and incentives for adoption rather than enforcement-oriented mechanisms for institutions outside the formal scope of the policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident-reporting and transparency provisions require careful balance. Serious incidents involving laboratory-acquired infection, meaningful loss of containment, environmental release, or potential community risk should clearly be documented and, where appropriate, made public.

However, broad public posting requirements for lower-level incidents could unintentionally discourage reporting. A strong biosafety culture depends on investigators, students, and staff being willing to report mistakes, near-misses, minor exposures, and procedural failures promptly. If individuals believe that every reported event may ultimately become part of a publicly accessible institutional record, there is a risk of creating incentives for under-reporting.

The draft itself recognizes the value of protected reporting by proposing confidential, de-identified submission of near-misses and other safety information to the National Biosafety Data and Safety Analysis Center. I encourage NIH to apply the same principle more broadly.

I recommend distinguishing among:

serious reportable incidents that warrant NIH notification and public transparency;
lower-risk incidents that require institutional review but not public posting; and
near-misses that should be encouraged through confidential, non-punitive reporting systems.

The templates should also minimize collection and disclosure of personally identifiable information and

should focus on the nature of the hazard, circumstances of the event, corrective actions, and lessons learned.

For meeting minutes, transparency is appropriate, but templates should avoid requiring unnecessary technical detail that could disclose confidential research information, security-sensitive information, or details that do not contribute meaningfully to public understanding of biosafety oversight.

The goal should be transparency that improves safety and accountability without undermining reporting culture.

6. Other feedback relevant to this resource: Implementation guidance will be critical because the proposed policy substantially expands both the scope of covered research and the responsibilities of institutions, IBCs, and investigators.

NIH should provide detailed guidance in several areas.

First, NIH should provide concrete examples distinguishing research requiring full IBC review, delegated review, registration-only oversight if such a category is adopted, and activities outside the scope of the policy. Routine examples from molecular and cell biology would be particularly valuable, including plasmid transfection, CRISPR-modified mammalian cell lines, stable and transient expression, replication-deficient viral vectors, reporter constructs, primary cells, and established cell lines.

Second, NIH should provide decision trees or risk-assessment tools that allow investigators and IBCs to determine the appropriate level of oversight and containment consistently.

Third, additional guidance is needed on how genetic modification should influence risk assessment, particularly when modifications attenuate rather than increase risk.

Fourth, NIH should clearly distinguish PI responsibilities from institutional responsibilities. Investigators should be responsible for appropriate conduct, training, supervision, risk assessment, and reporting. However, responsibility for institutional infrastructure, certification and maintenance of containment equipment, occupational health programs, and institutional safety systems should remain clearly assigned to the institution. The current draft assigns a broad range of responsibilities to PIs that could benefit from greater clarification.

Fifth, NIH should provide clear guidance on what constitutes a change requiring prior IBC review versus a minor modification that does not materially alter risk.

Finally, implementation resources should be designed with institutions of different sizes and research intensities in mind. A framework that works for an institution with extensive BSL-3 infrastructure may impose unnecessary burden on an institution conducting primarily BSL-1 and routine BSL-2 molecular and cell biology.

Overall, implementation guidance should reinforce the central principle that the degree of oversight and administrative burden should be proportional to the actual biosafety risk of the research.

15. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 8/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Given the intention to shift focus away from "red-tape" and to real risks, I am very surprised by a few things that now are no longer exempt from needing IBC review.

To now require the use of previously generated transgenic rodents to now be submitted to the IBC significantly increases the administrative burden on the PI, biosafety staff, and whichever committee member is delegated with no real benefit. Biosecurity (animal escape) is a consideration of the IACUC. I would argue you went the wrong way as I would have exempted purchase of all transgenic vertebrates (but I do appreciate the other animals now can be delegated rather than going to a meeting).

Also, it is unclear to me whether a human research protocol that involves a human blood draw now needs to go to a convened meeting (it seems to meet the definition of primary cells that could be contaminated by adventitious agents). That is a vast percentage of human studies and to make them go to a meeting seems to create a huge administrative burden when the OSHA bloodborne pathogen standard already prescribes precautions that must be in place.

I also don't know how we're going to keep track of every plasmid used in E. coli. Delegated member review is still a lot of regulation added where it wasn't before.

16. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 8/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Two incongruities in the tiered oversight are as follows:
- research involving genetically modified cells. It would be appropriate to differentiate research using previously modified cells (e.g. stable expressing cell lines) that are better placed in IV-3 than in IV-4 from generation of new genetically modified cells.
- similarly, genetic modifications of RG-2 pathogens that *decreases* virulence but still handled at BSL-2 would be more naturally placed with IV-4 than IV-3.
Implementing both of these changes would both give more consistent risk classifications and would incentivize institutions and investigators towards lower-risk activities when those are feasible (e.g. re-using previously generated cell lines and working with attenuated pathogens).

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The scope of public disclosure of research details before the research even begins has broad implications for both intellectual property and biosecurity. Public disclosure means that these can be scraped by AI agents by commercial and military adversaries of the United States and thus an incredibly granular picture of early-stage research will be obtained. This could be used to readily analyze and pre-empt NIH-funded research of commercial interest and also to target adversarial actions against the United States. Public reporting should be redacted and aggregated. There are two sets of concerns here - one is the United States public's interest in transparency. This would naturally focus on higher-risk research that carries risks for the public. This also has greater potential for non-commercial adversarial exposure (bioterror attacks, for instance). That is a trickier balance. For research that is low-risk to the public, the primary risks involve exposure of commercial information, either individually or at a large scale, that could be used both within the United States and, of particular national concern, by international commercial adversaries.

With the proposed disclosure, it would be easy to ask an AI agent "In what buildings and rooms are samples of virus X stored in city Y" or "analyze the disclosed activities of institution X and predict 10 future patent filings".

6. Other feedback relevant to this resource: N/A

17. Anonymous

I am responding: On behalf of myself

Name: Anonymous

Name of Organization: N/A

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 8/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: In the "Purpose; Background" section, it is stated "The feedback received to date has informed a new policy proposal that expands the scope of the NIH Guidelines to all biohazards while removing red tape for low-risk research," however, the new policy actually creates a truly significant amount of red tape for low-risk research in doing away with exemptions in Section III-F and Appendix C.
The draft policy lacks a category for exempt recombinant material, and therefore E. coli and S. cerevisiae protein expression experiments and work with previously exempt, commercially available transgenic rodents both read as explicitly included in Section IV-3, Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members.
If I'm not mistaken, this additional oversight represents a massive workload expansion, and the administrative burden is not commensurate with the risks of the research.
I urge the policy makers to re-implement the exemptions that were provided by Section III-F and Appendix C of the NIH Guidelines.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: What constitutes due diligence with regards to the review of formerly exempt research that is containable at BSL1/ABSL1?

18. Anonymous

I am responding: On behalf of myself

Name: Anonymous

Name of Organization: N/A

Type of Organization: Not Applicable

Role: Other

Date Submitted: 8/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: In the "Purpose; Background" section, it is stated "... NIH also seeks to strengthen the role of Institutional Biosafety Committees (IBCs) and reinforce consistency with Institutional Review Boards and Institutional Animal Care and Use Committees, which serve as three foundational pillars of institutional oversight of biomedical research."

By raising the incident reporting thresh hold to BSL3/ABSL3, the draft policy actually disempowers IBCs at institutions that do not have high containment research.

Incidents incurred during research containable at BSL2/ABSL2 ought to continue to be reportable to NIH.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

19. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 8/25/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The requirment to have 2 outside committee members is overbearing! Even the iACUC doesn't require that for animal research. Please consider just one.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

20. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 8/25/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: The continued use of risk groups as a baseline for the risk assessment is absolutely needed. Although they often coincide, there is a difference between the risks of exposure to an organism and the containment level assigned to perform specific procedures using the organism. Referring to biosafety levels to describe organisms causes confusion when that containment level needs to be raised or lowered due to the procedures being used when a non-pathogenic strain is used. Additionally, it is important for people to understand the risks of exposure to an organism. If the "rules" of determining the risk groups are maintained, saying that an organism means a very specific thing; similar to how saying that you need to use BSL-2 containment invokes several requirements related to PPE and facilities.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Meeting Minutes Template: The template is not clearly organized, and although it references sections of the Policy, those Policy sections do not match the required information in the minutes template notes column (e.g., inspections in Section III-B). Some of the sections that appear to be required for every meeting should instead be included as items to consider as "Other Business". Some examples
A. The template starts providing requirements for application reviews/discussions. But in the middle of what should be a discussion on a specific application, the template says you should record discussion of any delegated review approvals?
B. There is a section for "inspections/ongoing oversight". According to the [policy, the BSO is only required for BSL-3 and GDMO applications. So, is this only for those inspections? The Policy states that the IBC is responsible for reviewing the facilities. There are many ways, outside of an inspection, that the members can review the facilities as they relate to the work proposed, while allowing EHS to handle lab inspections outside of the IBC process and schedule.

C. IBC Training: Is the IBC expected to receive training every time they meet? If not, this should be part of "Other Business".

Incident Reporting: Requiring all incidents to be posted online will completely undo all efforts made to have cultures of safety and reporting between researchers and administrators, EHS, and occ. health when an accident occurs. Especially in academic institutions where students are involved with research. It has taken years of building trust, and helping researchers understand that reporting incidents is not for punitive measures, but to make sure that they are OK, and that the people, animals, and environment around them are OK, as a result of what has happened. And that review of what happened and updating related processes and procedures helps to mitigate future occurrences. Posting every incident online will be viewed, especially by students, as 100% punitive, and will ultimately result in people having incidents occur that go unreported because they didn't want it posted online. Keeping names out of the online publication is not enough to stop this from happening. I understand the need for transparency and would understand having to publish incidents that were risky enough they required submission to NIH, but publishing every incident online is the best way to cause issues that could have been contained or treated before they become disasters, become disasters.

6. Other feedback relevant to this resource: The Policy mentions GDMO several times, but that acronym is not defined anywhere (unless you are familiar with the NIH Guidelines). This needs to be included in the definitions.

The Policy references risk groups and mentions that the BMBL is a resource for determining risk groups. The BMBL does not have risk group lists. It mentions risk groups of some agents, but mostly references the NIH Guidelines appendices to obtain that information. Where will the currently assigned risk group determinations "live" when the NIH Guidelines cease to exist? The risk groups are an excellent base assessment and educational tool, and should not be dropped. But a reputable and trustworthy resource/website is needed, and needs to be referenced in the Policy.

21. Yefrenia Henriquez Taveras

I am responding: On behalf of myself

Name: Yefrenia Henriquez Taveras

Name of Organization: Weill Cornell Medicine

Type of Organization: Academic Institution

Role: Other

Role - Other: Research Compliance Administrator

Date Submitted: 8/27/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical research across multiple disciplines, including gene therapy, virology, and translational research.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: This is a substantial expansion of IBC jurisdiction. Many IBCs are currently staffed, trained, and resourced around rDNA and gene transfer review. Extending IBC review to all wild-type biological agent research, including agents already subject to overlapping oversight (institutional biosafety officers, occupational health programs, and in some cases the Federal Select Agent Program), will require institutions to substantially rebuild committee composition, agenda capacity, and administrative infrastructure well in advance of the proposed six-month effective date.

I recommend that NIH: (a) provide a transition period longer than six months for research newly brought into scope solely by the expanded biohazard definition, distinct from research already subject to the current Guidelines; and (b) clarify how this Policy's oversight is intended to interact with, rather than duplicate, existing institutional biosafety programs governed by OSHA bloodborne pathogen standards, the Federal Select Agent Program, and institutional occupational health services, particularly for wild-type agent research with no genetic modification component.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Section V-E acknowledges that RG and BSL are related but not equivalent, and that the appropriate BSL for a given experiment may be higher or lower than the RG of the source agent depending on genetic modification and manipulation. However, the Policy does not provide a decision framework for resolving this determination consistently across institutions.

In practice, this ambiguity falls to individual IBCs to resolve, which will produce inconsistent containment determinations for functionally similar constructs across institutions, undermining one of the Policy's stated goals of harmonized, transparent oversight. This is most acute for the multi-source construct scenario addressed in Section V-C, where an IBC must weigh RG classification, encoded function, and synergistic effect without a specified method for arriving at a final containment determination.

I recommend that NIH develop and publish, as part of the implementation resources referenced in the Policy, a structured decision tool or worked examples illustrating how RG classification, genetic modification, and manipulation risk are to be weighted against one another in arriving at a BSL determination, particularly for GDMO and synthetic construct research.

3. Continued utility of Risk Groups: Neither the current Guidelines nor this draft defines "surrounding community" by geography, and NIH has historically interpreted the phrase narrowly to require that non-affiliated members reside in or near the institution's local community. This interpretation has already led institutions to construct workaround arrangements, such as multi-institution reciprocal IBC agreements limited to geographically clustered institutions, in order to share qualified non-affiliated members rather than each recruiting independently.

As NIH is now modernizing the Policy and substantially expanding IBC jurisdiction to cover all biohazards, this is a natural opportunity to resolve the ambiguity rather than carry it forward unchanged. Institutions outside major research hubs, or those with multiple affiliated sites, face genuine difficulty recruiting qualified non-affiliated members under a strict local-residency reading, and the expanded scope of research subject to IBC review under this Policy will increase, not decrease, the demand on this pool of members.

I recommend that NIH either define "surrounding community" with explicit flexibility (for example, permitting non-affiliated members who reside within a defined regional area rather than strict local proximity), or expressly authorize multi-institution reliance arrangements for shared non-affiliated membership, particularly for institutions that are geographically proximate or under common administration.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Institutions that operate mixed research portfolios, including non-NIH-funded programs or affiliated entities that do not themselves receive NIH funds, have little practical basis for extending IBC oversight to those programs absent a defined mechanism.

I recommend that NIH consider concrete measures to support voluntary adoption, such as a public registry or attestation process for institutions extending Policy-consistent oversight to non-covered research, or guidance addressing how institutions may apply a single IBC review process across covered and non-covered research without creating inconsistent administrative records.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The Draft Incident Reporting Template instructs institutions not to include attachments, while Part 3 of the template calls for narrative detail sufficient to reconstruct the timeline, root cause, equipment or facility failures, and personal protective equipment performance associated with the incident. For incidents involving equipment failure or complex root cause analysis, supporting documentation (equipment logs, inspection records, laboratory diagrams) is often necessary to substantiate the narrative and support NIH's review, but the template as drafted precludes submitting it.

I recommend that NIH either permit limited supporting attachments for final reports (as distinct from initial 24-hour notifications), or clarify that institutions may reference underlying documentation

retained on file and available to NIH upon request, rather than requiring all substantiating detail to be captured in narrative form alone.

6. Other feedback relevant to this resource: NIH has indicated it will publish implementation resources addressing IBC functions, gene drive modified organism biosafety considerations, Risk Group classifications, and RG3 influenza-specific requirements. Two additional areas warrant implementation guidance given the Policy's scope:

First, Sections III-D and IV-1 direct institutions to petition NIH for containment determinations involving emerging, novel, or zoonotic agents without an available RG classification, and for initial requests to lower containment for RG3 or RG4 agents or GDMOs. The Policy states that NIH will review such requests "in a timely manner" but specifies no target turnaround. Because research subject to Section IV-1 cannot begin until NIH acts, an undefined review timeline creates planning uncertainty for institutions and investigators, particularly for time-sensitive or externally funded research. I recommend that NIH publish target review timeframes for Section IV-1 determinations, distinguishing routine requests from those requiring novel scientific assessment.

Second, Section III-A requires institutions to submit a written Biosafety Assurance approved by NIH before conducting any research subject to the Policy, renewable for periods of up to four years. The Policy does not describe a submission format, portal, or review timeline for this Assurance, unlike the Federalwide Assurance process OHRP has long maintained for human subjects research. Because the Policy's expanded scope will require many institutions to submit an Assurance for the first time, I recommend that NIH publish, as an implementation resource, a defined Assurance submission mechanism and an expected review timeline comparable to the OHRP FWA process.

22. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 8/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The requirement for each institution to report exposures on its public-facing website may incentivize individuals and/or organizations to not report exposure incidents. Reporting these privately to a regulatory agency, who could then publish aggregate statistics, may be a better alternative in that it would promote more rigorous incident reporting practices.

6. Other feedback relevant to this resource: N/A

23. Kathleen George

I am responding: On behalf of myself

Name: Kathleen George

Name of Organization: WCG

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): human gene therapy clinical trials

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Period of IBC oversight. The update states that oversight may conclude after the last participant is administered the final dose. For clinical trials, the study agent is often present at the institution for a long time after last dose. The site will need send the agent back to the sponsor or dispose of it at the site. Storage, transport, and biohazard waste management should still be reviewed by the IBC until the agent is no longer at the institution.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I wasn't aware of NIH biosafety education until I read about it in the update. I think its great that NIH provides biosafety education, however, the education should be more prominently promoted so biosafety personnel are aware of its existence.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

24. Anna McLoon

I am responding: On behalf of myself

Name: Anna McLoon

Name of Organization: Siena University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Molecular microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Hello,

I am a member of the IBC at Siena, and I am confused about how to apply the updated guidelines to these situations:

1. What about work with organisms like Bacillus subtilis or Saccharomyces cerevisiae that are generally recognized as safe? These do not meet the definition of "biological agent" so does that mean work with GRAS organisms are exempt from oversight? Or does any project with transgenic yeast or Bacillus subtilis require approval before initiation?

2. All language here is focused on research, but across the country, recombinant DNA, genetically modified animals like fruit flies, and biological agents are often used in teaching laboratories. What are expectations about registration and oversight of projects that are carried out in the teaching laboratory? These do not fit under the definition of research. Do ALL teaching exercises require individual approval, or are they not covered by the guidelines intentionally?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Are the new policies purposely getting rid of the category that previously just required submission at the time of initiation? This is unclear.

For smaller, teaching focused institutions, these guidelines are a bit hard to interpret in terms of how much oversight is needed for basic-science research or teaching laboratory activities with organisms with

no real threat to researcher or community (GFP expressing zebrafish, gene knockout strains of yeast, etc.). More guidance about low-risk cases would be helpful, especially any ways to simplify the process for educators and researchers, which will help increase understanding and compliance.

25. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 9/2/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): University of Missouri-Kansas City

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The expanded scope : from recombinant/synthetic nucleic acid molecules to any biomedical research involving wild-type human pathogens, genetically modified organisms, toxins/prions, or agents containing these, represents a substantial broadening of institutional oversight responsibility. While closing genuine gaps (e.g., wild-type pathogen work that previously fell outside IBC purview) is a reasonable goal, the definition as drafted creates ambiguity that will produce inconsistent institutional interpretation:

The phrase "known or potential risk to human health" is not quantified or bounded. Institutions need clearer thresholds (e.g., does BSL-1 wild-type work with no meaningful pathogenicity in immunocompetent hosts fall under the policy, or only agents with a defined risk group designation?). "Self-aggregating proteins" as a category alongside toxins and prions is vague, this could sweep in basic protein-folding research never intended for biosafety oversight. NIH should provide a non-exhaustive list of covered agent classes or a decision-tree tool.
There is no explicit treatment of in vitro diagnostic reagents, environmental/wastewater surveillance samples, or clinical specimens of unknown infectious status, all of which are common in academic biomedical research and sit in a gray zone under the proposed definition.
We recommend NIH clarify whether human cell lines or patient-derived samples that are not genetically modified but carry endogenous or adventitious agents (e.g., primary tissue with unknown viral status) fall within scope, since "cells... that have been genetically modified" is explicit but non-modified but potentially infectious samples are not addressed.

Without this clarification, institutions will apply inconsistent scoping determinations, undermining the goal of national consistency this policy is meant to achieve.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The general direction; delegating more RG2-level containment decisions to the IBC while retaining NIH review for RG3/RG4, is appropriately risk-calibrated in principle. However, several elements of the tiering warrant reconsideration:

Local IBCs vary widely in technical capacity and available expertise across institutions of different sizes. A tiering scheme that assumes uniform IBC sophistication nationally risks inconsistent risk management at smaller or resource-limited institutions that lack in-house biosafety expertise to responsibly exercise newly delegated authority (e.g., approving containment reductions or exercising delegated review) without an NIH backstop.

The tiering of incident reporting (NIH-reportable vs. institution-only) is a reasonable federal/local split for genuinely low-risk events, but the criteria for the local tier (e.g., "agent-specific treatment beyond basic first aid") require more precise, auditable definitions to prevent under-reporting or inconsistent classification across institutions

3. Continued utility of Risk Groups: Risk Groups remain a useful baseline for intrinsic agent hazard (transmissibility, severity, availability of treatment) but are increasingly poor proxies for actual risk once genetic modification is introduced. We recommend the following:

RG classifications are typically assigned to wild-type organisms and do not automatically capture risk changes from genetic modification (e.g., host range expansion, enhanced transmissibility, altered virulence, or novel gain-of-function characteristics). The policy should require an explicit, documented risk reassessment for any genetically modified derivative of an RG-classified agent, rather than allowing the parental RG designation to be inherited by default.

BSL/ABSL, by contrast, reflects the containment and practice controls actually applied to mitigate risk in a given experimental context, and is a more operationally meaningful metric for day-to-day IBC and reporting purposes (as reflected in the incident-reporting tiers, which are BSL-based, not RG-based).

The final policy should explicitly state that RG is a starting point for hazard identification, not a substitute for a documented, agent- and modification-specific risk assessment, and that containment decisions (BSL/ABSL) must be justified by that assessment rather than derived mechanically from RG. This is particularly important for the newly delegated review categories (e.g., "RG1 genetically modified biological agents"), where a low starting RG could mask a significant risk change introduced by the modification itself.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Because the Policy remains a term and condition of NIH award (not a general regulatory requirement), non-NIH-funded entities conducting comparable biohazard research have no obligation to comply, creating an uneven national biosafety landscape. To encourage voluntary adoption:

NIH could develop a formal "recognition" or attestation program allowing non-federally-funded institutions to publicly certify adherence to the Policy, which would carry reputational and partnership value (e.g., for institutions seeking to collaborate with NIH-funded partners or attract sponsored research).

NIH could tie eligibility for future funding mechanisms, training grants, or NIH-sponsored biosafety resources (e.g., the mandated templates, technical assistance) to demonstrated voluntary compliance,

creating an incentive short of a funding mandate.

Providing the compliance templates, training materials, and model assurance language freely and prominently (not gated behind an active award) would lower the barrier for non-funded institutions to adopt the framework voluntarily, particularly smaller institutions without the administrative capacity to build a compliance program from scratch.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting template should include a clearly delineated field for the reporting tier determination (NIH-reportable vs. institution-only) with the specific criterion cited, to create an auditable record of why an incident was or was not escalated to NIH, this supports consistency review and reduces ambiguity in borderline cases.

The incident template should include a structured field for corrective action and follow-up verification, distinct from the initial incident description, so that both NIH and the public (given the new public-posting requirement) can see resolution status, not just the initial event.

The mandated meeting minutes template should accommodate institution-specific business (e.g., local policy items unrelated to federal reporting) as an optional addendum section, rather than forcing all IBC business into a federally-defined structure. Without this flexibility, institutions may end up maintaining two sets of minutes (one for federal compliance, one for internal governance), duplicating administrative effort.

Both templates should be released in an editable, structured electronic format (not PDF) compatible with common IBC/protocol management software, to avoid a costly manual re-entry burden across institutions transitioning from existing systems.

6. Other feedback relevant to this resource: This is my most significant concern with the draft as a whole, and I urge NIH to address it before finalization.

The Policy's requirement that all incidents : including those that remain institution-only and never reach NIH, be posted to a public-facing institutional website represents a substantial departure from current practice, where only NIH-reportable incidents are subject to public disclosure (via FOIA request, which involves a review and redaction process). We are concerned this requirement, as drafted, will have the opposite of its intended effect:

Chilling effect on self-reporting. Laboratory personnel are the first line of incident identification. If staff know that even minor, appropriately-managed events (e.g., a needlestick with only first-aid treatment, an animal bite) will be published publicly and potentially attributable to their lab or specific personnel, institutions should reasonably expect a decline in voluntary self-reporting, the opposite of the transparency and safety-culture goals the policy intends to advance. Underreporting of "minor" events is also how institutions typically identify systemic or trending risks before they escalate; suppressing that data pipeline undermines proactive safety management.

Absence of privacy/redaction standards. The draft does not specify what level of detail must be publicly posted, whether personally identifiable information (employee names, specific lab locations, treatment

details) must be redacted, or who is responsible for reviewing postings for privacy and legal compliance before publication. Without this guidance, institutions face genuine legal exposure (potential HIPAA-adjacent issues, workers' compensation implications, and defamation/privacy tort risk) and will likely respond by either over-redacting postings to the point of uselessness or, more likely, under-reporting or delaying disclosure while legal review occurs, undermining the timeliness the policy seeks.

No defined retention or format standard. The draft does not specify how long postings must remain public, whether they must be updated as investigations conclude, or in what format (searchable log vs. static PDF) they must appear, this ambiguity will produce widely inconsistent public transparency across institutions, undermining comparability.
Recommendation: NIH either (a) limit the public-posting requirement to incidents that meet the NIH-reportable threshold, consistent with current FOIA-based public availability, and allow institution-only incidents to remain within existing institutional safety/HR reporting channels; or (b) if public posting of all incidents is retained, issue detailed guidance on required redaction standards, a standardized aggregate/de-identified reporting format (e.g., annual summary statistics rather than incident-level detail for the lowest tier), and a defined review and retention process, developed in consultation with institutional legal counsel, biosafety officers, and IBC chairs before finalization, given the direct tension between public transparency and the self-reporting behavior the biosafety oversight system depends on.

Additional implementation guidance would also be valuable on: (1) a model SOP or decision criteria for delegated review to promote consistency across institutions exercising this new authority for the first time; (2) clarification of the "higher risk manipulations" threshold referenced for clinical research triggers; and (3) a transition timeline and grace period for institutions to complete the scope-gap analysis, revise IBC charters, and build new public-reporting infrastructure before enforcement begins.

26. Shubhashish Sarkar

I am responding: On behalf of myself

Name: Shubhashish Sarkar

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/3/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): All types of biomedical research.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The inclusion of wild type organisms for biosafety oversight is a right step taken by NIH and is much appreciated. This will be beneficial to safeguard the researchers and the environment. However, the policy gives a vague approach towards identifying the dangerous organism that will need a biosafety oversight. It is difficult to understand who will decide the pathogenicity of any organism an investigator wants to use in research. Will NIH revise the existing databases or create a totally new database with additional organisms.
The policy has emphasized genetic modification of any kind that will result in pathogenicity of an organism or vice versa. However, changes in growth conditions or other environmental factors are also associated with pathogenicity of an organism (Fierer J, Looney D, Pechère JC. Nature and Pathogenicity of Micro-organisms. Infectious Diseases. 2017:4–25.e1. doi: 10.1016/B978-0-7020-6285-8.00002-2. Epub 2016 Aug 12. PMCID: PMC7173513.). Are these exempted modifications ignored?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

27. Jennifer Hill

I am responding: On behalf of myself

Name: Jennifer Hill

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 9/3/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am concerned that the proposed scope would unintentionally bring substantial amounts of routine, low-risk biomedical research under IBC oversight without a corresponding biosafety benefit. One example is the proposed requirement for review and approval of research conducted with transgenic organisms at BSL-1/ABSL-1. This appears to encompass routine use of established genetically modified mouse lines, including commercially available Cre, floxed, knockout, and reporter strains that have been developed, characterized, and widely used by the research community. In most experiments, the genetic modification does not itself create a meaningful biosafety hazard. A laboratory may purchase an established transgenic mouse line and use it to study normal physiology, metabolism, behavior, or responses to pharmacologic treatments. Requiring IBC approval solely because the animal carries a defined genetic modification would add another regulatory layer to studies that may present no greater biosafety risk than comparable experiments in wild-type animals.

I encourage NIH to retain an exemption or establish a categorical exclusion for established transgenic rodent lines maintained and used at ABSL-1 when the genetic modification does not reasonably increase risk to human health or the environment. IBC oversight would be more appropriately focused on genetic modifications that materially alter pathogenicity, toxicity, transmissibility, environmental persistence, host range, or another characteristic relevant to biosafety.

I am also concerned that the proposed definition of "toxin" is broad enough to encompass ordinary endogenous proteins and peptide hormones. The draft defines a toxin as a "protein or peptide produced by living organisms that causes harm in humans." Taken literally, this could include insulin, since insulin is a naturally produced peptide hormone and inappropriate exposure or administration can cause severe hypoglycemia. The same ambiguity could extend to other peptide hormones, cytokines, growth factors, and physiological signaling molecules. It seems unlikely that routine administration of insulin in an animal physiology experiment is the type of biological-toxin research NIH intends to place under IBC oversight, but the proposed definition does not clearly exclude it.

I recommend revising the definition of toxin so that it clearly distinguishes recognized biological toxins from endogenous proteins, peptide hormones, cytokines, growth factors, and similar physiological molecules used in routine biomedical research. The definition should focus on inherent toxic activity or established biosafety classifications rather than simply whether a protein or peptide can cause harm under some exposure condition.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed use of delegated IBC review for lower-risk research is a useful mechanism for reducing burden, but delegated review does not fully address the underlying problem if very low-risk activities are unnecessarily brought within the policy in the first place. Routine use of an established ABSL-1 transgenic mouse line should not require IBC approval simply because the animal is genetically modified when the modification has no plausible effect on biosafety risk.

A risk-calibrated system should distinguish between research that warrants oversight and research that is sufficiently low risk to be categorically excluded. Delegated review is appropriate for research that presents a low but non-negligible biosafety risk. It should not substitute for an exemption where there is no meaningful biohazard to assess. NIH should therefore consider explicit exclusions for established ABSL-1 transgenic rodent lines whose genetic modifications do not increase biosafety risk, while retaining IBC review for modifications that alter characteristics relevant to human, animal, or environmental safety.

3. Continued utility of Risk Groups: Risk Groups and Biosafety Levels remain useful frameworks for biological agents for which pathogenicity, transmissibility, routes of exposure, and containment are meaningful considerations. However, neither framework by itself resolves the problem of applying biosafety oversight to routine genetically modified animals or physiological proteins that do not present hazards analogous to infectious agents.

For these categories, the risk assessment should focus on whether the particular genetic modification, protein, or experimental manipulation actually changes the risk of harm to research personnel, the public, or the environment. The mere presence of a genetic modification in an ABSL-1 mouse should not itself be treated as evidence of increased biosafety risk.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed incident-reporting requirements could have unintended consequences when combined with the expansion of the policy to routine ABSL-1 transgenic animals. The draft identifies events such as bites, scratches, animal escapes, and improper disposition involving animals used in research subject to the policy as incidents requiring IBC review. If an ordinary commercially available transgenic mouse is now considered covered research solely because it is genetically modified, a routine mouse bite, scratch, or escape could become an IBC-reportable incident even when the genetic modification has no relationship to the risk posed by the event.

This could generate substantial administrative reporting of events that do not represent meaningful biosafety incidents. The requirement for public posting of finalized incident reports further increases the

consequences of classifying very low-risk events in this manner. NIH should distinguish incidents involving an actual biohazard from routine animal-handling events in which the covered characteristic of the animal did not contribute to the hazard. Incident reporting should be calibrated to the biological risk posed by the event rather than triggered solely because the animal happens to fall within the policy's broad scope.

6. Other feedback relevant to this resource: Additional guidance would be particularly valuable in several areas created by the expanded scope of the policy. NIH should clearly define which established transgenic rodent lines require IBC review and whether routine breeding, colony maintenance, and experiments involving commercially available Cre, floxed, knockout, and reporter lines are intended to be covered. NIH should also define what constitutes a "low-risk transgene" for purposes of delegated review of viral-vector research.

Most importantly, NIH should provide explicit guidance on the meaning of "toxin." The current wording could reasonably be interpreted to include endogenous peptide hormones such as insulin and potentially many other physiological proteins that can cause harm at sufficiently high doses. Implementation guidance should make clear whether such compounds are outside the intended scope. Preferably, this distinction should be incorporated directly into the policy definition rather than left solely to subsequent guidance, since inconsistent institutional interpretations could otherwise lead to substantial variation in IBC oversight.

NIH should also clarify how incident-reporting requirements apply to routine ABSL-1 transgenic animal research. If NIH intends standard transgenic rodent lines to remain within the policy, guidance should distinguish events that actually implicate the genetic modification or another biohazard from ordinary animal-handling incidents that pose no additional biosafety risk because the animal is transgenic.

28. Jenifer Coburn

I am responding: On behalf of myself

Name: Jenifer Coburn

Name of Organization: Medical College of Wisconsin

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/4/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): pathogenic microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I do not believe that it is appropriate to require public posting of Institutional Biosafety Committee (IBC) members' names. This is due to concerns regarding some members of the public targeting individuals at work and/or at home. These sorts of attacks may be rare but the population of those who believe that this is legitimate appears to be growing.

For the same reason, I do not believe that the Principal Investigator's name should appear in the IBC meeting minutes. I suggest that the PI's name be redacted. Laboratory personnel names should not be included in any public-facing document or website.

Why is genetic manipulation of plants not considered potentially risky to human health? Humans eat plants.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

29. Partha Krishnan

I am responding: On behalf of myself

Name: Partha Krishnan

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 9/4/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Recombinant DNA

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft expands coverage to include wild-type pathogens, genetically modified organisms, toxins, prions, and other biohazards, rather than focusing primarily on recombinant nucleic acid research. This better aligns oversight with contemporary synthetic biology, gene editing, and emerging pathogen research. Can the definition of biohazard be so broad to encompass any agent - living or dead of biological origin that causes a threat to the healthy human condition?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Institutions receiving NIH funding would be required to ensure compliance for all covered research conducted at their institution, regardless of funding source. The proposed Biosafety Assurance mechanism may improve institutional ownership of biosafety programs.

3. Enhanced Transparency

The requirement to publicly post IBC meeting minutes and incident reports could substantially improve public trust and enable cross-institutional learning from biosafety events

3. Continued utility of Risk Groups: Move toward a multi-factor risk framework including:

Agent characteristics
Modification type
Experimental procedures
Exposure potential
Scale of work
Environmental consequences
Availability of countermeasures

Benefit : Traditional RG classifications may not adequately capture risks from genetically modified or synthetic organisms.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Mandate Near-Miss Reporting
Issue :The policy emphasizes incidents but provides less clarity on systematic near-miss reporting.

Recommendation : Create tiered reporting requirements:

Near miss - Institutional database
Significant near miss- NIH database
Exposure/release - Immediate NIH notification

High-reliability industries (aviation, nuclear power) derive tremendous safety benefits from near-miss analysis before harm occurs.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting template is comprehensive and supports the policy goals of transparency and accountability. However, several enhancements could improve its value for institutional learning and national biosafety analysis.

1. Add Structured Near-Miss Reporting

Comment: The template focuses on reportable incidents but does not explicitly capture near misses.

Recommendation: Add a field:

Was this:
Incident
Potential exposure
Near miss
Unsafe condition

Rationale: Near misses provide some of the most valuable opportunities for prevention and are a cornerstone of high-reliability safety programs.

2. Strengthen Root Cause Analysis Requirements

The current template requests a root cause description and corrective actions.

Recommendation: Require categorization of root causes:

Human factors
Training deficiency
SOP deficiency
Equipment failure
Facility failure
Organizational/process failure

Communication failure
Risk assessment deficiency

Benefit: Facilitates trend analysis by the proposed National Biosafety Data and Safety Analysis Center.

3. Track Contributing Factors Separately

Recommendation: Add a section:

"Contributing Factors (check all that apply)"

Fatigue
Workload
Time pressure
Staffing shortage
Inexperience
Inadequate supervision
Equipment design
Environmental conditions
Other

Reason: Most incidents arise from multiple factors rather than a single root cause.

4. Add Risk Severity Classification

Recommendation:

Include:

Actual Consequence
No impact
Minor injury
Medical treatment
Laboratory-acquired infection
Environmental release
Potential Consequence
Negligible
Low
Moderate
High
Severe

Benefit: Improves national comparisons and prioritization of corrective actions.

5. Include Corrective Action Effectiveness Review

Currently, corrective actions are documented, but effectiveness is not evaluated.

Recommendation:

Add:

Responsible person
Implementation date
Verification method
Follow-up review date
Effectiveness assessment

This ensures corrective actions are not merely documented but validated.

6. Improve Biosecurity Capture

Recommendation:

Add specific fields addressing:

Inventory discrepancy
Unauthorized access
Security breach
Suspected misuse
Cybersecurity-related laboratory event

This would better integrate biosafety and biosecurity.

7. Clarify Public Transparency Expectations

The template appropriately promotes public transparency using lay language.

Recommendation:

Provide:

A public summary section (1-2 paragraphs)
A technical section for NIH review

This balances transparency with technical completeness.

Comments on Draft_IBC-Meeting-Minutes-Template.pdf

The template is thoughtfully designed and likely represents a major improvement in transparency. It should, however, provide additional structure to improve consistency across institutions.

1. Add a Safety Culture Review Section

Current minutes focus on protocol review and compliance activities.

Recommendation:

Include a standing agenda item:

Biosafety Program Metrics
Number of incidents
Number of near misses
Laboratory inspection findings
Training completion rates
Outstanding corrective actions

Benefit: Promotes proactive oversight rather than reactive incident review.

2. Require Documentation of Risk-Benefit Discussions

The template requests risk assessment discussion, but not the rationale for acceptability of risk.

Recommendation:

Add:

Risk-Benefit Rationale
Key risks identified
Mitigation measures
Scientific value
Reason risks were considered acceptable

This improves transparency and consistency.

3. Capture Emerging Technology Considerations

The broader biosafety policy explicitly addresses novel organisms and AI-enabled synthetic biology.

Recommendation:

Include a review prompt:

Emerging Technology Considerations
Synthetic biology
Gene editing
Gene drives
AI-assisted biological design
Novel organisms

Helps ensure consistent review of future technologies.

4. Improve Conflict of Interest Documentation

The template requires disclosure of conflicts but provides limited detail.

Recommendation:

Document:

Name of conflicted member
Nature of conflict (general category)
Recusal confirmed
Member absent during vote

This strengthens transparency.

5. Require Documentation of Containment Justification

The template records assigned biosafety levels.

Recommendation:

Add:

Containment Justification
Basis for containment selection
Deviations from standard guidance
Enhanced containment measures

This improves consistency and auditability.

6. Add Oversight Tracking Dashboard

For each meeting include:

Metric NumberActive protocols
New protocols reviewed
Amendments reviewed
Deferred reviews
Open incidents
Closed incidents
Conditional approvals

This enables institutions and NIH to identify trends over time.

7. Add Corrective Action Tracking

The current format discusses incidents and inspections but lacks formal tracking.

Recommendation:

Create a standing section:

Open Corrective Actions
Description
Responsible party
Due date
Status

This supports continuous improvement.

8. Clarify Redaction Standards

The template permits redaction of private, proprietary, or security-sensitive information while emphasizing transparency.

Recommendation:

NIH should publish:

Standard redaction guidance
Example acceptable redactions
Example unacceptable redactions

This would improve consistency across institutions.

6. Other feedback relevant to this resource: I am submitting a manuscript to Applied Biosafety with the abstract below for a NEW biosafety paradigm moving away from regulation based checklists

Abstract

Ensuring safe operation of research and clinical laboratories requires a structured, repeatable, and rapid method for assessing baseline safety conditions.2–5 Traditional inspections and audits, while essential, are often time intensive, episodic, and dependent on the expertise of individual reviewers.4,5,9,10 This creates variability in safety assessments and delays in identifying critical gaps. To address this challenge, a simplified, four domain scoring system designed to provide an immediate snapshot of facility safety readiness is proposed. The SAFE Score evaluates Signage, Awareness, Facility, and Emergency Equipment, assigning each a score from 0 to 2. The total score (0–8) functions as a “safety vital sign,” analogous to the APGAR score used in pediatrics to rapidly assess newborn health.1,6 Like APGAR, the SAFE Score is not a substitute for comprehensive evaluation but serves as a standardized, rapid triage tool that determines the urgency of intervention and guides next steps.1,6 This article presents the conceptual foundation, development, and application of the SAFE Score, explores its parallels with the APGAR framework, and demonstrates how it can transform laboratory safety culture by enabling consistent, data driven decision making.7,9,13

Draft of manuscript is attached.

Uploaded File: SAFE_Score_Research_Article_SAGE_Format.pdf

The SAFE Score: A Rapid, Standardized Framework for Assessing Laboratory Safety Readiness

Abstract

Ensuring safe operation of research and clinical laboratories requires a structured, repeatable, and rapid method for assessing baseline safety conditions.[2–5] Traditional inspections and audits, while essential, are often time-intensive, episodic, and dependent on the expertise of individual reviewers.[4,5,9,10] This creates variability in safety assessments and delays in identifying critical gaps. To address this challenge, a simplified, four-domain scoring system designed to provide an immediate snapshot of facility safety readiness is proposed. The SAFE Score evaluates Signage, Awareness, Facility, and Emergency Equipment, assigning each a score from 0 to 2. The total score (0–8) functions as a "safety vital sign," analogous to the APGAR score used in pediatrics to rapidly assess newborn health.[1,6] Like APGAR, the SAFE Score is not a substitute for comprehensive evaluation but serves as a standardized, rapid triage tool that determines the urgency of intervention and guides next steps.[1,6] This article presents the conceptual foundation, development, and application of the SAFE Score, explores its parallels with the APGAR framework, and demonstrates how it can transform laboratory safety culture by enabling consistent, data-driven decision-making.[7,9,13]

Introduction

Laboratory environments—academic, industrial, clinical, and commercial—are dynamic systems where people, procedures, equipment, and materials interact continuously. Safety in these settings is not a static achievement but an ongoing operational requirement that must be actively managed at every level of the organization. Engineering controls, administrative policies, and written procedures form the backbone of a safe laboratory, but they are effective only when paired with routine verification, clear communication, and a culture that prioritizes readiness. When any of these elements weaken—through staffing turnover, deferred maintenance, or simple human complacency—the probability of incidents rises, often in ways that are subtle and cumulative rather than dramatic and immediate.

Traditional safety programs rely heavily on formal audits, regulatory inspections, and incident investigations. These activities are indispensable for ensuring compliance and for uncovering systemic weaknesses, but they share common limitations: they are episodic, resource-intensive, and often scheduled far enough apart that small degradations can go unnoticed. An annual or semiannual audit can document compliance at a point in time without revealing the day-to-day drift that precedes many near misses and accidents. Moreover, audits frequently depend on the expertise and judgment of individual inspectors, which introduces variability in findings and in the prioritization of corrective actions. For organizations that operate multiple sites or diverse laboratory types, this variability complicates comparisons and obscures broader trends.

To address these gaps, safety programs need tools that are rapid, repeatable, and standardized tools that convert qualitative observations into quantitative signals that can be trended, compared, and acted upon. The SAFE Score proposed here as a framework meets that need. By condensing readiness into four universal domains—Signage, Awareness, Facility, and Emergency Equipment—and scoring each domain on a simple 0–2 scale, SAFE produces a single, interpretable metric that functions as a "safety vital sign." This metric is intentionally lightweight so it can be collected frequently by a range of observers, from EHS professionals to laboratory supervisors and trained frontline staff, without the need for lengthy checklists or specialized audit teams.

The design philosophy behind SAFE draws directly from successful rapid-assessment models in other high-risk fields. The APGAR score in neonatology is a paradigmatic example: a short, standardized assessment that does not replace comprehensive clinical evaluation but provides an immediate, reproducible trigger for intervention as to whether a newborn baby, minutes after birth, is adapting well to life outside of the womb. SAFE adopts the same architecture—few domains, simple scoring, and clear triage thresholds—so that a low score prompts predefined actions rather than protracted deliberation**.** This reduces the time between detection and remediation and embeds a culture of immediate, evidence-based response into routine operations.

Each SAFE domain was chosen for its universal relevance and its capacity to reveal early signs of degradation. **Signage** communicates hazards and controls; missing, illegible, or incorrect signs are often the first visible indicator of broader lapses in maintenance or oversight. **Awareness** captures the human dimension: whether personnel recognize hazards, know where to find controls, and can articulate basic response steps. Awareness deficits frequently precede unsafe behaviors even in well-equipped facilities. **Facility** assesses the presence and functionality of engineering controls—ventilation, containment devices, and certified equipment—that materially reduce exposure risk. Finally, **Emergency Equipment** evaluates whether eyewash stations, showers, fire suppression, spill kits, and other critical resources are present, accessible, and operational. Together these domains provide a balanced view of communication, human factors, infrastructure, and emergency readiness.

The practical advantages of a standardized, short-form tool are multiple. First, frequent SAFE assessments create a continuous data stream that enables trend analysis, early detection of seasonal or staffing-related patterns, and objective evaluation of interventions such as training or maintenance programs. Second, a numeric, color-coded output simplifies communication across organizational levels: a single dashboard can show which units are trending toward risk and which require immediate attention. Third, standardization reduces inter-rater variability and allows aggregation of results across sites, which is essential for organizations that must allocate limited EHS resources strategically.

At the same time, SAFE is explicitly designed to complement—not replace—formal audits and regulatory reviews. Short-form assessments are inherently reductive and cannot capture the full complexity of systems, documentation, and procedural compliance that comprehensive audits examine. To mitigate this limitation, SAFE should be integrated into a broader governance framework that includes periodic comprehensive audits, cross-audits for calibration, and

mechanisms for verifying the accuracy of routine assessments. Training, inter-rater reliability checks, and periodic recalibration of scoring criteria are essential to maintain the tool's validity and usefulness.

Finally, the cultural implications of adopting a tool like SAFE are significant. When safety readiness is measured frequently and communicated clearly, it becomes part of everyday work rather than an occasional administrative burden. A simple, repeatable metric empowers frontline staff to participate in safety monitoring, creates transparent accountability, and fosters a proactive approach to risk reduction. In an era of increasing laboratory complexity, staffing pressures, and regulatory scrutiny, embedding rapid, standardized readiness checks into routine practice offers a pragmatic path to more resilient, safer laboratory operations.

Background and Rationale

Laboratory safety is an ongoing operational requirement, not a one-time compliance exercise. Traditional audits and regulatory inspections are essential but episodic, resource-intensive, and subject to inter-inspector variability, which limits their ability to detect early drift in day-to-day readiness. Standardized, short-form assessments convert sporadic checks into continuous monitoring, enabling organizations to detect small but consequential degradations (e.g., faded signage, uninspected eyewash stations, or lapses in personnel awareness) before they escalate into incidents. Frequent, standardized checks also create comparable data streams that support statistical monitoring, targeted interventions, and evidence-based resource allocation.

The SAFE Score operationalizes these principles by reducing laboratory readiness to four universal domains—Signage, Awareness, Facility, and Emergency Equipment—each scored 0–2**,** producing a single 0–8 metric that is easy to record, interpret, and trend. The SAFE Score provides a rapid, structured, and standardized method for assessing laboratory safety readiness. By evaluating four essential domains—Signage, Awareness, Facility, and Emergency Equipment—the SAFE Score enables organizations to identify gaps early, track trends over time, and cultivate a proactive safety culture.

Why mirror APGAR? The APGAR score's enduring utility in neonatology stems from five attributes: simplicity, universal applicability, rapid execution, reproducible scoring, and direct linkage to immediate actions. APGAR's 0–2 per-item scale and clear triage thresholds trained clinicians to act quickly and consistently; it did not replace comprehensive neonatal assessment but provided a standardized trigger for urgent intervention. Adopting the same architecture for laboratory safety means a low SAFE Score triggers predefined escalation steps rather than subjective debate, shortening the time from detection to remediation and embedding safety triage into routine workflows.

Standardization reduces variability and enables aggregation. A numeric, color-coded SAFE Score creates a common language across units and institutions, allowing EHS teams to aggregate

results, identify systemic weaknesses, and measure the impact of corrective actions. This is consistent with contemporary biosafety guidance that emphasizes protocol-driven risk assessment and repeatable controls as foundations for laboratory safety programs.[8,14]

Practical benefits and limitations.

SAFE assessments take minutes, require minimal training, and produce data suitable for dashboards and predictive trend analysis. **They are best used as a complement—not a replacement—for formal audits**: frequent SAFE checks maintain operational readiness while comprehensive audits evaluate systems, documentation, and compliance in depth.[11,12] Limitations include potential oversimplification of complex hazards and dependence on honest observation; these are mitigated by periodic calibration, cross-audits, and integration with incident reporting and formal audit cycles.

Implementation essentials:

To realize SAFE's value, organizations should adopt standardized scoring sheets, train assessors, define governance for escalation thresholds, and integrate scores into EHS dashboards. Over time, aggregated SAFE data can reveal seasonal patterns, staffing impacts, and the effectiveness of training—turning a simple triage tool into a predictive element of a mature safety program.

Quick comparison (key attributes)

Attribute	APGAR	SAFE
Purpose	Rapid newborn triage.	Rapid lab safety triage.
Domains	5 clinical signs.	4 safety domains.
Scoring	0–2 per item; total 0–10.	0–2 per domain; total 0–8.
Action	Immediate clinical interventions.	Immediate safety escalation and remediation.

Conclusion

The SAFE Score provides a rapid, structured, and standardized method for assessing laboratory safety readiness. Modeled after the APGAR score in pediatrics, it serves as a "safety vital sign" that guides immediate action without replacing comprehensive inspections. By evaluating four essential domains—Signage, Awareness, Facility, and Emergency Equipment—the SAFE Score enables organizations to identify gaps early, track trends over time, and cultivate a proactive safety culture. As laboratories face increasing complexity, staffing challenges, and regulatory

scrutiny, tools like the SAFE Score offer a practical and scalable approach to ensuring safe operations.

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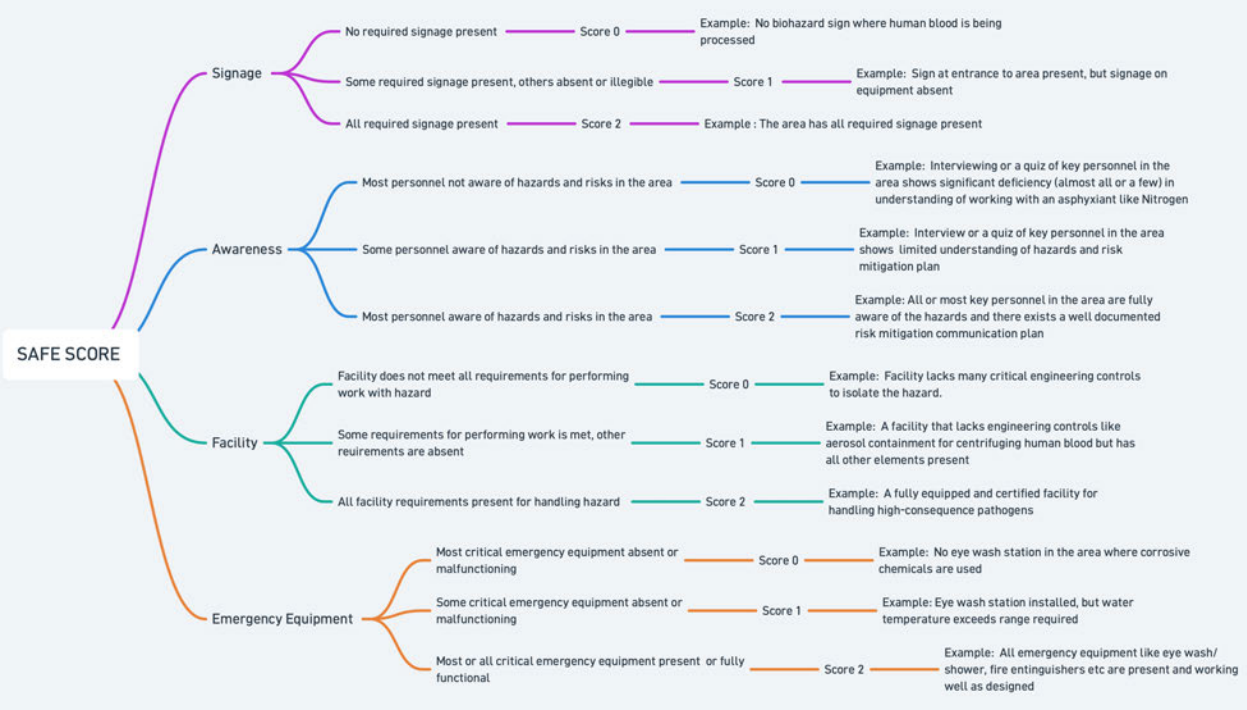


Figure 1. SAFE Score domain map. Schematic representation of the four SAFE Score domains: Signage, Awareness, Facility, and Emergency Equipment. Each domain is assessed using a 0–2 scale to generate a cumulative score ranging from 0 to 8. The framework is intended to provide a rapid, standardized indication of laboratory safety readiness by linking observable field conditions to a concise readiness metric.

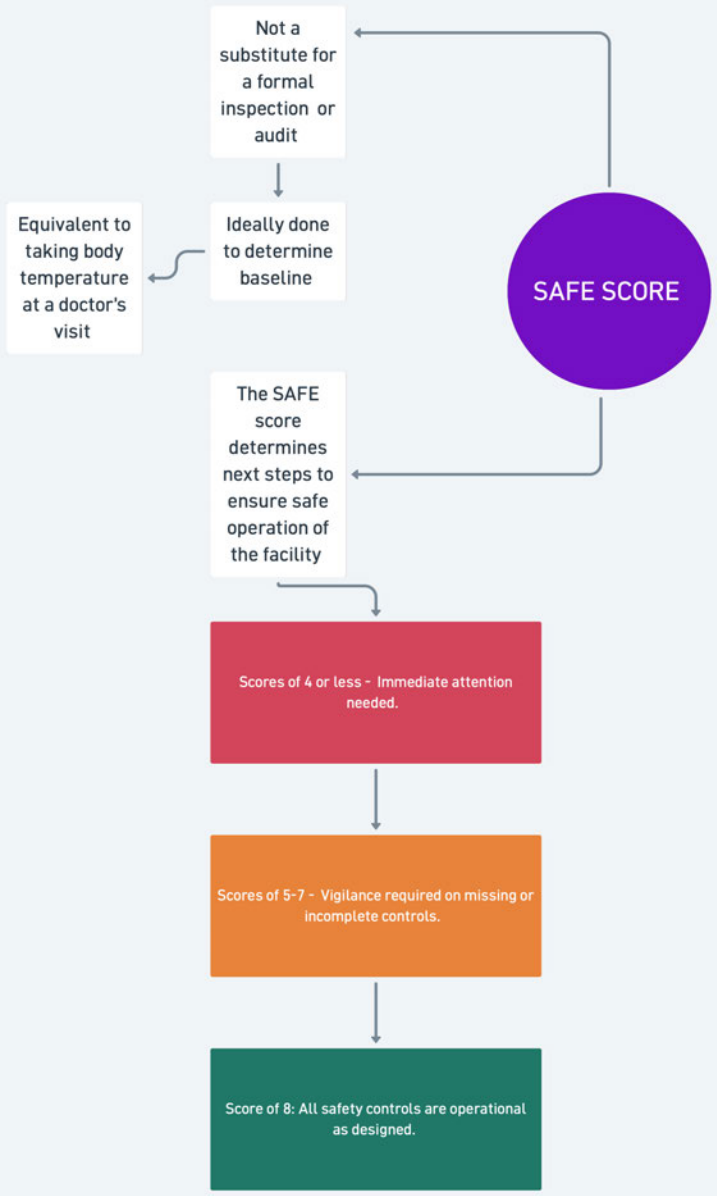


Figure 2. SAFE Score triage and response framework. Proposed interpretation of SAFE Score results as a decision-support tool for laboratory safety readiness. Higher scores indicate acceptable readiness with routine monitoring, intermediate scores indicate the need for targeted corrective action and reassessment, and lower scores indicate urgent escalation and immediate remediation. The framework links numeric scoring to predefined response thresholds to support consistent safety decision-making.

30. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/4/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): cancer, infectious diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: It is unclear why this updated biosafety policy is needed or improves the safety of laboratory members and the public. Current standards are rigorous and appropriately applied for all research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Risk groups are appropriate and do not need to be replaced with biosafety levels.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

31. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/4/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cardiovascular basic/translational research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The major problem is that these definitions of biohazards are overly broad, and will in effect be like catching dolphins in the tuna nets. The first and third criteria are understandable and indeed would classify as biohazards. Applying this as done in #4 is then fine as well. However, #2 is a catchall - essentially any genetically modified model, cellular, viral, bacterial, or organism (i.e. animal) is considered a biohazard. This is not true, the vast majority of these conditions that are widely used in virtually all basic science laboratories in all fields do not pose any biohazard to humans in anyway. The mutations engineered are designed to alter the function of a protein or gene itself, they are then used to study molecular signaling, disease mechanisms, potential therapeutic avenues, etc.. None are transmissible and/or toxic to humans in anyway. Many of these are readily purchased by commercial entities, such as Jackson Labs for mouse models, or VectorBuilder and other companies for viruses that express mutated genes to form altered proteins. Many are made in our own laboratories using commercial kits and then used in cell culture or other experiments to study the molecular biology involved. If every one of these uses is now going to require the extensive documentation, surveillance, and oversight-approval from the academic institution and the PI investigator, this will amount to a huge time and administrative burden that will not result in any change in national or personal security. The administrative structures that are identified - both federal and local - should be applied to REAL RISKs - e.g. those entities that are in fact true biohazards. Labs that are involved with these types of materials already have procedures and administrative oversight in place and if these could benefit from added security by additional oversight - I am all for that. But for the 99.9999% of labs that routinely use genetically engineered models at molecular, cellular, or organ levels for their research, none of which pose biohazards to the investigators, the university where the studies are being done, or to the nation or world - there needs to be a much more rational filter. Most all activities involving modification of DNA or genes to alter cellular function used in biological studies do not impose any biohazard risks, and are simply current state of the art scientific approaches to doing the top level science. Imposing major complex administrative structures, demands, oversight, public postings, as proposed will only cripple the pursuit of cutting edge biological science in the U.S..

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

32. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Healthcare Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/6/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): human health care

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am concerned that new policy does not cover Wild-type biological agents that cause diseases in non-human animals ABSL2 or higher. I feel this is an area missing oversight in the guidelines.

I greatly appriate the oversight WT agents that are biohazards in humans in addition to genetically modified agents

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Time time for full implantation would be great. Also how general human blood that is assumed to be infectious is classified under the policy.

33. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Healthcare Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/6/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): human health care

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am concerned that the language stating "research with primary cells that may be contaminated by adventitious agents" could be interpreted to include all research involving human blood and blood products. Because human blood and blood-derived materials are generally treated as potentially infectious, this wording may unintentionally capture a broad range of routine research activities.

I agree that appropriate review of the biosafety measures associated with the use of human blood and blood products is necessary, particularly because these materials may contain infectious agents of unknown status. However, I believe the policy should clarify that routine research involving human blood and blood products, when conducted under appropriate institutional biosafety practices, may be eligible for review and approval by an individual or subgroup of IBC members.

Adding this clarification would help distinguish routine work with human blood and blood products from research involving specific biological agents or other activities that warrant full IBC review. I believe this would reduce potential confusion and provide greater consistency in how the policy is interpreted and implemented.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

34. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Healthcare Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/6/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): human health care

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft policy should clearly state whether the BMBL remains an advisory document recommending best practices for safe biomedical and clinical laboratory work, or whether it is intended to function as a regulatory document establishing mandatory standards.

I am particularly concerned that removal of the physical-containment appendix could be interpreted as allowing reduced or discretionary physical containment. The policy should explicitly clarify that the Physical Containment Levels outlined in the BMBL are required standards, not optional recommendations, where applicable. Removal of the appendix should not be interpreted as eliminating or reducing these requirements.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

35. Bruce O'Hara

I am responding: On behalf of myself

Name: Bruce O'Hara

Name of Organization: University of Kentucky

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Neuroscience, neurological disorders, sleep and circadian rhythms

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Existing policies are more than sufficient to ensure reasonable safety. Please STOP adding more admin burdens. Admin burdens have increasingly impacted my research, teaching, and service for more than 40 years. Each one seems small, but they are now a tremendous drain on productivity in my view, and have led me to cease several research products due to the increasing demands. These proposed policies clearly add more, and more unnecessary burdens.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): see above comment

3. Continued utility of Risk Groups: see above comment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): see first comment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: see first comment

6. Other feedback relevant to this resource: Once again, I believe exisiting policies are already sufficient, and in fact already too burdensome. Please do nothing to add more burdens.

36. Brittany Belin

I am responding: On behalf of myself

Name: Brittany Belin

Name of Organization: University of Kentucky

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The expansion of the biological toxins beyond Select Agents and Toxins is concerning. Arguably, most cell types will produce some type of toxin under some conditions, depending upon how the term "toxin" is defined. We also do not know the composition of the secretions of every cell type under every condition, and so it is difficult to even assess whether a molecule meeting the expanded definition of a "toxin" is being produced. Significantly more clarity on the definition of biological toxins and how to assess whether they are present is required.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The requirement to report exposure incidents within 24 hours is far too extreme. This will create an extreme burden on every IBC, and it is not clear that it would lead to any meaningful improvements in safety.

6. Other feedback relevant to this resource: N/A

37. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 9/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Way too broad for large institutions. There is no money for this.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Absolutely ridiculous. No one has time or money for this nonsense.

6. Other feedback relevant to this resource: Would need at least 2 years to implement.

38. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/10/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): microbiology and immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I don't see why human materials that may be contaminated with bloodborne pathogens need IBC oversight. The OSHA bloodborne pathogen standard lays out requirements for this work, so this is a huge increase in administrative burden with no tangible increase in safety from what was already in place.

Toxins behave more like chemicals than biological agents and the controls used for their safety reflect that. Safety Data Sheets are available for them. Their inclusion seems out-of-place. Many IBCs do not include chemical safety experts and chemical safety experts do not have the expertise to comment on other types of biohazards.

There was a reason that transgenic rodents were exempted previously. The draft policy explicitly says work with transgenic animals at (A)BSL-1 requires delegated member review and I do not see rodents exempted. We anticipate 100-200 investigators who never were required to submit previously to now have to write and submit an IBC protocol, which then have the be reviewed by our IBC analysts and delegated IBC members. What is the increase in safety? Animal escape is already under the IACUC purview.

I do appreciate inclusion of macaque materials that may be contaminated with Herpes B. By including them, you are closing a gap since that wasn't covered by an existing mechanism.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I appreciate the intent of increasing information disclosure, but the level of details needed for that extremely thorough template makes drafting the minutes a full FTE's worth of work. We timed it and it takes 40 more

minutes PER PROTOCOL to draft minutes that fit this template. This is an unfunded mandate. Currently, we redact almost nothing from our minutes, but if we need to put in some of these specifics, our legal counsel will redact a lot of it to protect active research.

Similar to the old NIH Guidelines, you could have made it mandatory that we release a full protocol by request if someone saw something in the minutes they wanted more information on. That would keep the information channels open, but not require this huge increase in administrative burden that may or may not have any real effect.

For incident reports, if someone is given a PI's name and the injured person's position and gender, it is often easy to narrow it down to 1 or 2 people with some internet sleuthing. I am concerned about the effect this will have on an injured person reporting to us. We try to make this process as non-punitive as possible, but if I were a researcher and made a silly mistake, I would be deterred from reporting if I knew my mistake would be published on a public website.

6. Other feedback relevant to this resource: I really need to know if it was your intention that "research with primary cells that may be contaminated with adventitious agents" include any human research protocol with a blood draw. Requiring those protocols go to meeting would add upwards of 50-80 protocols for committee review per month, when they are using precautions (Universal or Standard Precautions) reviewed by the IRB and dictated by the OSHA Bloodborne pathogen standard.

If transgenic mice need a protocol now for DMR, are we supposed to review every strain of transgenic mouse, or can approval be given for work with any transgenic mice that don't require ABSL-2? This is a huge group of people who never had to submit a protocol in the past and this makes a real-world difference in the administrative burden.

I understand the intent of a de novo submission, but our electronic protocol system has a tight connect for IRB studies and their associated IBC protocols. It will take a major development project to be able to close an IBC and reopen another for an IRB project that was approved and is ongoing. If it was just a de novo review without forcing a protocol to close and reopen, wouldn't you still get the intended fresh eyes on it? What does closing the protocol significantly add?

39. Fred M. Cowan

I am responding: On behalf of myself

Name: Fred M. Cowan

Name of Organization: Uppsala Inc.

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Investigator/Researcher

Date Submitted: 9/11/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Immunotherapy and AI Governance

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Checkpoint Governance for NIH Biosafety Oversight
Fred M. Cowan | President, Uppsala Inc. | 11 September 2026
Response to NOT-OD-26-112 — Draft NIH Biosafety Policy for Research Involving Biohazards

I recommend that NIH incorporate explicit, auditable decision checkpoints into its final biosafety policy and implementation guidance. The draft already provides tiered oversight, Institutional Biosafety Committee (IBC) review, and incident reporting. Checkpoint governance could help connect these provisions to verifiable conditions for proceeding, reconsidering, or stopping research. The practical question is whether a warning changes what happens next. AI innovation can provide a failsafe checkpoint system for biotechnology, AI safety and surety and many other applications.

My background includes U.S. Army Special Forces service (1969–1971) and approximately three decades of government biomedical research at the National Institutes of Health (NIH) and the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD). My research in addition to checkpoints in immunotherapy and AI, spans chemical and biological countermeasures, including active/passive immunotherapy (API), disclosed in WO2001032207A1 as a proposed strategy for recruiting pre-existing immunity against selected targets, including infectious agents and toxins [11].

Lara Marks's history of immune-checkpoint inhibitors explicitly includes our NCI Fc-receptor studies and 1979 patent among the field's early developments [4,8]; checkpoint immunotherapy now constitutes a multibillion-dollar therapeutic field [6]. Our Multi-Threat Medical Countermeasures work articulated an injury-focused approach across chemical threats [5]. BARDA's chemical program now applies that central principle through broad-spectrum treatment and drug repurposing [7], while a 2024 HHS paper describes shared chemical and radiation injury mechanisms under "multi-utility" countermeasures [9]. These connections inform our broader checkpoint review [2].
Biological checkpoints illustrate how context-dependent activation and inhibition can preserve useful responses while limiting injury. Our pseudo-conscience proposal translates this regulatory principle into

a functional governance layer for detecting harmful trajectories, prompting restraint, and escalating unresolved concerns [12]. Applied to NIH oversight, AI could compare policy with evidence, flag inconsistent classifications or unsupported exceptions, track unmet approval conditions, and trigger accountable reconsideration. The PCT architecture supplies the proposed question-review, memory, provenance, and externalization controls [3]. This is an analogy and design rationale for evaluation; policy authority remains with accountable human institutions, and protective effectiveness must be demonstrated.

The coupling of AI capability with biological misuse makes biosecurity, including bioterrorism prevention, a direct checkpoint-governance application. Anthropic's September 2026 threat report describes five cases of AI use potentially supporting biological weapons development and attempts to evade safeguards; it does not assert that the researchers intended harm [10]. This supports evaluating the architecture proposed in PCT/US2026/036247 [3] as an additional layer governing passage from biological requests to released guidance or consequential action. Its protective value against biological misuse remains to be established.
The need for operational clarity is documented. In 2023, GAO found that an undefined review standard allowed potentially inconsistent interpretations of which proposals involving enhanced potential pandemic pathogens required departmental review [1]. A checkpoint should identify the decision, required evidence, responsible authority, and conditions that require escalation. I suggest five implementation priorities.

1. Review the question before authorizing the work. A Question Airlock should document the scientific objective, expected benefit, safer alternatives, assumptions, and material uncertainty. Review should consider relevant historical evidence and adverse findings, with unavailable information identified. Building on Section V, NIH should provide worked examples showing how agent characteristics, modifications, experimental context, and uncertainty determine oversight. Risk Group classification should inform this judgment without substituting for assessment of the proposed work.

2. Record a decision that controls passage. For each consequential transition, record GO, REVISE, HOLD, or WITHHOLD, with reasons and a named authorizing official. A compact Return Packet should preserve supporting evidence, provenance, unresolved concerns, alternatives, dissent, and approval conditions. GO should require verification that the applicable conditions are met. Implementation should support independent review and documented conflict recusals. A local checkpoint cannot authorize work prohibited by applicable requirements.

3. Keep approval responsive to changing evidence. Supplement scheduled reviews with explicit triggers for reassessment, including unexpected findings, containment failures, protocol changes affecting risk, and overdue information material to safety. Predetermined triggers should pause the affected activity and route the concern to the appropriate authority. Record who must respond, by when, and what evidence permits resumption. Preserve decision versions and the disposition of earlier warnings so that staff turnover or project continuation does not erase unresolved concerns.

4. Govern the transition from AI output to action. Guidance should address AI-assisted research as a coupled human, software, and laboratory workflow. A Question Airlock should review purpose and

cumulative context; the Return Packet should preserve evidence, warnings, and provenance. An Externalization Airlock should prevent release of high-risk guidance or execution of laboratory actions without independent, accountable authorization. Record relevant model and tool versions, evidence limitations, and the responsible reviewer. Enforce permissions outside the generating model, because a malicious or mistaken human operator may be part of the threat. Neither model confidence nor a human signature alone establishes that the required safety conditions have been satisfied.

5. Make learning and proportionality measurable. Use the proposed near-miss learning system to feed lessons back into checkpoint criteria, while preserving mandatory reporting and accountability. Provide common templates, training, and interoperable records usable by smaller institutions and voluntary participants. Pilot these measures against existing practice, including adversarial attempts to bypass controls, assessing time from warning to protective action, recurring failures, closure of safety conditions, and unnecessary delays to low-risk work. Interpret reporting rates in light of reporting culture; more reports alone do not establish worse safety.

Over my career, my work has benefited from millions of dollars in taxpayer-funded resources. That investment warrants scrutiny of both my claims and how institutions evaluate and preserve the resulting knowledge. Claims that exceed evidence require revision; potentially useful findings that were overlooked warrant examination. Checkpoint governance should make the evidence, unresolved questions, and reasons for advancing, deferring, or discontinuing work traceable.

NIH can specify these functions without requiring a particular vendor or patented implementation. The objective is earlier, accountable reconsideration while preserving useful research. The speed and cost of self-correction are themselves measures of how well science is working.

References and disclosure

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Disclosure: I am an applicant on PCT/US2026/036247 and have an interest in the proposed architecture. OpenAI ChatGPT assisted with preparation of this comment; I retain responsibility for the final submission.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

40. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Research Participant/Patient/Advocate/Caregiver

Date Submitted: 9/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): AI

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

41. Marcia Espinola

I am responding: On behalf of myself

Name: Marcia Espinola

Name of Organization: University of Cincinnati

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 9/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer biology, neurobiology, infectious and metabolic diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The overall scope of this new policy aligns well with our IBC scope. However, several key areas require further clarification, particularly regarding human clinical research protocols. I have attached a detailed document highlighting these specific items.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The tiered review seems appropriate.

3. Continued utility of Risk Groups: I agree with this approach. Starting with the Risk Group as the baseline makes complete sense. Once you assess the specific modifications to the agent and the nature of the planned activities, you can effectively assign and adopt the biosafety containment level and practical safeguards described in the BMBL.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): They seem proper to me.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Minutes - I support the effort to bring consistency to meeting minutes, but I have concerns regarding the required level of detail for some sections of the template (i.e. Project Overview and Risk Assessment). For example, for protocols involving multiple agents, documenting full agent description and mitigation plans for each of them will make the minutes overly dense and create a heavy administrative burden for the IBC staff. More importantly, including this depth of information risks exposing proprietary intellectual property. The level of details required in this template essentially reflects the entire protocol. Instead, these two sections should be replaced by a section to simply list the research items that apply to the policy, avoiding unnecessary detail while protecting Intellectual Property and streamlining workflow.

Incident Report – I believe the template itself works well, as it is very similar to the current version. While I appreciate the intent to promote public transparency, I am concerned that this policy may have

unintended consequences internally. Establishing and sustaining a non-punitive reporting culture remains a significant challenge, and considerable effort is continuously invested in encouraging staff to report incidents openly and without fear of repercussions. Knowing that these reports may be made public, even in redacted form, could discourage reporting, reduce internal transparency, and ultimately undermine the safety culture we are continually working to improve.

6. Other feedback relevant to this resource: Additional implementation resources would definitely promote consistent interpretation and implementation across institutions. This could include an expanded General Definitions section, examples within the Scope section, a FAQ document with representative scenarios, a decision tree for determining applicability, training materials or webinars to support institutions during the initial implementation phase and address common questions.

ADDITIONAL COMMENTS:

Scope - The four items listed in the Scope section are ambiguous with respect to clinical research involving human subjects. Additional language in further section adds to this confusion. For example, the “General Definitions” section states that "laboratory research" includes clinical settings. It is unclear whether what is listed in the Scope section is intended to include clinical research. In fact, the term “clinical research” is referenced only in Section IV-2. Also, because some institutions conduct veterinary clinical research, the document should specify whether the term “clinical research” refers solely to human clinical research. To address these inconsistencies, I recommend relocating information about human clinical research within the “Scope” section and clearly defining the scope requirements and applicability of the policy to clinical research activities.

Scope #1 - Specify the exact human population subject to this policy. Please clarify whether this applies strictly to healthy adult human subjects or extends to vulnerable populations, pediatric subjects, or specific clinical patient cohorts.

Scope #2 - For clarity, I recommend replacing the term “organisms” with “animals and other organisms” and providing representative examples to clearly define the intended scope.

General Definitions - This section should be moved to the beginning of the document rather than appearing midway through the text. Placing definitions upfront would improve readability and provide readers with the necessary context before encountering specialized terminology. Additionally, rather than defining only “Gene Drive”, the document should provide a definition for “Gene Drive Modified Organisms” (GDMOs). The acronym GDMO is used throughout the document without first presenting the full term or defining it when initially introduced.

Section IV-2
a) Specify the scope of primary cell sources and potential adventitious agents. It is not clear if this requirement applies strictly to human-derived primary cells or includes any other sources. Also unclear is whether adventitious agents are limited to pathogens with human tropism or extended to broader host ranges.

b) Clinical Protocols - As mentioned previously, to avoid confusion, I the applicability of human clinical protocols should be included in the Scope section instead.

● The reference to “products” in the second bullet is unclear and should be defined. Does this term include any biological product used in clinical (e.g. monoclonal antibodies, purified proteins) submitted to higher risk manipulation? If the intent is to refer only to the products described in the first bullet, the information should be rather incorporated into the first bullet to avoid confusion.
● Is that correct to assume that CAR-T cell clinical studies and mRNA vaccines no longer apply to this policy and don’t need IBC registration?
● What is the rationale for limiting the scope to RG2 WT agents? While biosafety programs are often focused on protecting the health professional, some RG1 organisms can pose significant health risks to immunocompromised patients.

Section IV - 4
a) Clarification is needed regarding NIH requirements for biological containment of transgenic animals. Does NIH require biological containment for any transgenic animals, or only when animals are exposed to microbiological agents, consistent with BMBL animal biosafety level definition?

b) What source of “well -characterized cells” apply to this section?

Description: I cannot see the document I've tried to attach being uploaded. Therefore, I've entered my additional comments in the #6 field

42. Mitchell Berger

I am responding: On behalf of myself

Name: Mitchell Berger

Name of Organization: None

Type of Organization: Not Applicable

Role: Other

Role - Other: Commenting in personal capacity

Date Submitted: 9/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Public health, behavioral health, emergency preparedness

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Commments on policy-potential changes to scope and definitions

1. Risk Management (Section V)
Add language stating that risk assessment should consider:
personnel competency and experience; supervision; compliance history;
incident/near-miss history; institutional safety performance.

This is especially important for work involving elevated consequences or uncertainty.

2. Definition of Acceptable Risk
Section V refers to “acceptable” risk without defining it. The policy should clarify:

acceptable vs. tolerable vs. unacceptable risk; how uncertainty affects the determination;
who has authority to determine residual risk is acceptable.

3. Gain-of-Function Research
The biosafety policy should explicitly align with NIH gain-of-function policies and address:
how NIH will coordinate review for research subject to both frameworks;
how NIH will prevent projects from avoiding higher-level oversight due to differing definitions;
how cross-agency jurisdiction works when another federal agency is involved.

The current language (“may proceed under the oversight of the other federal agency”) is too vague and risks gaps in oversight.

4. FDA Expanded Access IND — One Participant Exclusion
The policy excludes from NIH review any clinical product administered to one participant under an FDA

expanded access IND. Clarify:
why one participant is sufficient to exclude NIH review;
whether FDA will review biosafety aspects of such use.

5. Approval Duration
The policy's three-year approval limit may be too long for some studies and too short for others. Approval duration should be based on risk (e.g., BSL, agent characteristics, uncertainty), not a single fixed period.

6. Stop-Work Mechanism
Add an explicit stop-work provision allowing immediate suspension of research when:
conditions differ from those under which approval was granted, or an unacceptable risk is identified.
Clarify who can issue the order, how it is communicated, and how research may resume.

7. Definitions, Novel Agent
The definition of "novel agent" is too narrow. Recommend:

"Novel agent or organism: An agent or organism not existing in nature, deliberately designed, or newly arising through recombination or other processes, including those not intentionally engineered."

8. Definitions, Emerging Agent
The definition should reflect that agents may become higher-risk even if not newly identified. Recommend:
"Emerging agent or organism: An agent or organism that is newly identified, newly recognized as presenting significant human/animal/environmental risk, or whose epidemiological, pathogenic, ecological, or other characteristics have materially changed."

9. Definitions, Biological Agent
The current definition excludes several important categories. Recommend:
"Biological agent: Bacteria, viruses, fungi, parasites, prions, toxins, gene-drive modified organisms, insects or arthropods capable of transmitting disease, and other agents capable of causing human, animal, or environmental harm."

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Meeting minutes template
1. Investigator/Laboratory Compliance and Safety History
The current template captures basic principal investigator information (training, incidents, inspections, protocol details), but it does not ask the IBC to document whether the PI or laboratory has a relevant compliance or safety history. A dedicated field should be added:

Relevant Investigator/Laboratory Compliance and Safety History
(Including prior significant biosafety incidents; repeated or unresolved deficiencies; previous IBC required conditions;
completion and effectiveness of corrective actions; prior experience with the proposed hazard or containment level.
Including this information helps ensure the minutes reflect any history that may influence risk assessment or oversight.

2. Incident Documentation
The existing field ("Document any incidents…") should be expanded so the minutes capture more than a simple notation. Recommended additions include:
root cause and contributing factors; corrective and preventive actions (CAPA); responsible person/office; expected completion date;
verification of completion; assessment of effectiveness.

This level of detail supports the purpose of the minutes as both an institutional record and evidence that the IBC is meeting its oversight responsibilities.

3. Biosafety Level Assignment
The template asks for "Biosafety Level Assignment" and the "Basis for containment determination." It should also briefly explain why the committee selected a particular BSL (e.g., why BSL-2 was chosen instead of BSL-3, or why enhanced practices were considered adequate).

4. Risk Assessment — Uncertainties
The minutes should note key uncertainties discussed during review, such as:
limited data on the modified agent; uncertain host range; insufficient evidence of attenuation; uncertainty about environmental stability;
uncertainty about the effectiveness of proposed mitigations.

The minutes should also describe how the IBC addressed these uncertainties (e.g., conditions, monitoring requirements, restricted procedures).

5. IBC Vote — Clarification Field
In addition to "For/Against/Abstain," add: Significant Unresolved Concerns Raised During Review

This is useful when votes are close or heavily one-sided and helps clarify the nature of concerns that influenced the vote.

6. Conflicts of Interest
The template should request more detail, including: nature of the conflict (financial, employment, personal relationship);
whether the member recused themselves from the proceedings;
whether they abstained, voted, or participated in discussion.

7. Delegated Review
The “Readout of Any Projects Approved by Delegated Review” field should include:
a short description of the work; the approval decision; any conditions imposed; a brief explanation of why the protocol qualified for delegated review.

8. External Facilities/Services/Materials
Add a field documenting external facilities or services relevant to biosafety (e.g., specialized animal facilities, waste contractors, external labs). This is important when IBC conditions depend on external entities.

Incident reprot template comments:
1. Outcome of Incident
Add a field describing the outcome, such as: medical treatment; hospitalization; no treatment required; fatality;
long-term disability or morbidity; environmental or public-health impact.

If unknown, note: “Outcome currently unknown/pending follow-up.”

2. Lessons Learned
Add a field asking what lessons were learned, including whether the incident revealed gaps in training, procedures, equipment, facility design, supervision, risk assessment, or safety culture.

3. Cost/Economic Impact
Add a field for cost or economic impact.

4. Corrective Actions vs. Preventive Actions
Separate immediate corrective actions from longer-term preventive actions. Preventive actions may include supervision changes, SOP revisions, or engineering controls.

5. Effectiveness of Actions
Add fields for: implementation date; whether actions were effective; how effectiveness was evaluated; whether similar incidents recurred.

6. Recurrence/History
Add: “Has a similar incident, near-miss, deficiency, or SOP deviation occurred previously at this institution or laboratory?”

7. Known vs. Unknown Information
Because investigations may be ongoing, add fields for:

Known; Unknown/pending investigation; Not applicable.

The template can be updated later when the investigation is complete.

6. Other feedback relevant to this resource: N/A

43. Helen Scharfman

I am responding: On behalf of myself

Name: Helen Scharfman

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Co-Chair of Institutional Biosafety Committee

Date Submitted: 9/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The term biohazards needs clarification regarding incident reporting.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Unclear what is meant.

3. Continued utility of Risk Groups: This is fine.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reports that are proposed carry an immense burden on the institution and investigators because of the detail proposed in the new reporting guidelines that need to be posted and in the minutes. The minutes have details that are redundant to what is already in the approved protocol. Repeating this in specific ways will be a huge burden on the institution and investigators.

6. Other feedback relevant to this resource: N/A

44. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 9/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: '-I feel like there should be additional oversight for the clinical setting. Specifically, first in human genetic-based clinical products and genetic-based products with no previous clinical experience should be monitored by the IBC. We do not thoroughly understand the risks with these study agents and IBC guidance would be valuable. Additionally, the definition of higher risk manipulation is open to a wide range of interpretation. I would consider the use of sharps as a higher risk manipulation, but others might not.
-I did not see a mention of the size of the genetic alterations. Is it understood to be any size of stable genetic alteration, even very few base pairs?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: I agree with the continued use of RGs instead of BSL. Risk groups are more universally used and define the agent itself, while BSL is defining more of the precautions. Other countries, such as Canada, have studies that require IBC oversight, but they use Containment Levels, not BSLs. It also provides more levels of risk assessment and institutional policy.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I thought this section was good. I think the NIH guidelines are a good framework for all research, so that was well addressed.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It was unclear to me if institutions should be using that exact minutes templates or if it was just a guidance for suggested or required sections. The draft policy makes it seem like the exact template is required, but the minutes themselves feel less certain. Also, is there the ability to modify the minutes template to remove non-applicable sections or is the requirement to put “NA” for these sections?

6. Other feedback relevant to this resource: '-In a clinical setting, “respiratory protection” usually means the requirement to have a fit-testing program, so they can require N95s. Is this the requirement or was it meant to be a more general statement? Universal precautions does not generally include respiratory

protection, but instead focuses on protection against human bodily fluids, so mucus membrane protection is what is commonly used. This is achieved through PPE like face shields, eye protection, and face masks, instead of “respiratory protection.”
-It would be helpful to have more guidance on redacting. I know the document requests the sites provide their redaction policy, but it would be very helpful to have a template policy for them to start with. It is also unclear what items are allowed to be redacted.
-I have concerns about the public availability of the information regarding institutions that conduct “research in a BSL3/ABSL-3 or BSL4/ABSL-4 laboratory, research with GDMOs” on the institution’s website. Making this information publicly available on their website could potentially put them at greater risk for a biosecurity attack. It would be safer to have this information with the roster on the NIH, but not publicly available.

45. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Scope: The NIH Guidelines had some experiments that were low-risk, and therefore exempt. Since only wild type RG1 organisms and modified plants are exempt from this policy, do institutions need to have all work involving cloning in RG1 E. coli and yeast reviewed by the IBC (or a delegated review)? This needs to be clarified in the policy, to alleviate confusion with those that have been following the NIH Guidelines. A section with what is exempt should be included, even if it is only RG1 wild type biological agents and modified plants.

2. Section II
A. The definition of "disease", as pertains to this policy, is needed. For example: The wild-type biological agents and the toxins statements do not say "other than plants". For this reason, would poison ivy and/or urushiol be considered to cause a disease in humans and therefore be applicable to the policy? This type of information needs to be clarified, clearly explained, throughout the policy.

B. "other than plants" in the scope statements in all sections needs to be better defined. For example, scope statement 2 says that "Cells, viruses, or organisms, other then plants, that have been genetically modified" are applicable to the policy. Does this mean that modification of plant leaves, cells, tissues, as well as whole plants are not applicable to the policy; or, does "other than plants" only refer to whole plants?

3. Section IV-2
A. Statement 2 (research involving genetically modified cells, viruses, or organisms) does not state any risk groups, containment levels, or pathogenesis. Therefore, it appears that all genetically modified cells, viruses, or organisms (other than plants) need IBC review and approval. However, Section IV-3 then states that modified RG1 biological agents and certain viral vectors can be part of a delegated review. This is confusing.

4. Section IV-3

A. Statement 3 says that research with transgenic organisms at BSL-1/ABSL-1 can be reviewed as part of a delegated review. And so, if delegated review is not used they would need to be reviewed by the full committee. Does this mean that the purchase, breeding, and use of all transgenic mouse strains obtained from a vendor have to be reviewed by the IBC, even for experiments that don't involve administration of biological agents?

B. Statement 3 involves research with transgenic organisms. Transgenic means a transgene was inserted. Does this statement refer to those specific organisms, or does it refer to all modified organisms generated by any means (e.g., transgenes, site-directed mutagenesis, conditional expression, CRISPR, etc.)? Transgenic needs to be defined.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: 1. Risk Groups are a valuable tool for risk assessments, and for educating students, researchers, and the public about biological agents. Modifying an organism for research itself does not change the risk group. Trying to develop an attenuated organism does not mean the organism has lower risks. It still needs to be tested, which is why they are referred to as "candidates" during research. However, established and tested strains, FDA approved vaccines, or commercially available attenuated agents should be reviewed to determine if those specific strains can have a different risk group (as is already done and listed in the NIH Guidelines Appendix B).

2. 3rd and 4th generation replication deficient lentivirus viral vector systems (vectors themselves; nothing to do with the target genes being expressed) should be reviewed to have the risk group lowered to RG2. Depending on the genes being expressed, the containment levels would need to be assigned.

3. The published policy needs to include access to risk group designations. Without access to the information (the BMBL does not provide useful risk group information), implementing and being compliant with Section IV-1 is impossible.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: 1. Section III-A states that "No research subject to this Policy may be conducted until the institution conducting the research has provided a written Biosafety Assurance through the Authorized Organizational Representative (AOR) that has been approved by NIH, setting forth compliance with this Policy."
A. There is no information provided related to where and how the institutions submit the assurance.
B. There is no information describing when the assurance would need to be submitted in relation to the timeline of this Policy, and how long approval from NIH will take.
C. As this is a new policy, no institution has an approved biosafety assurance at this time. Does that mean that all NIH funded work applicable to this policy is expected to stop when the policy is published, or will there be an implementation time-frame in place, specific to the approved assurances, that takes into account the NIH's ability to review and approve all of the assurances that will be submitted when the policy is launched?

46. Daniel Kiss

I am responding: On behalf of myself

Name: Daniel Kiss

Name of Organization: not applicable

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 9/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): nucleic acid therapeutics

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: My major concern is that this new policy will enshrine an incorrect (and dangerous) definition of genetic modification as official NIH policy. I have quoted the problematic language below:

Genetic modification:
• The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:

• Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or

• Have the potential for one or more cycles of replication in a cell; or

• Can be transcribed or translated; or

• The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.

All prior definitions of genetic modification have centered on techniques and experiments that caused changes to the genomic DNA/RNA of the host cell, virus, or organism. However, as the text above shows, this proposed policy change ignores that decades-old scientific consensus. As the new language includes nucleic acids that “Can be transcribed or translated” this policy will incorrectly classify the vast majority of vaccine technologies as Genetic modification even though no vaccine platform alters the genome of the recipient.

For example, under this definition, all mRNA vaccines (whose sole function is to be translated into antigen protein that trains the immune system), all virally-vectored DNA vaccines (like the Oxford-AstraZeneca COVID-19 vaccine that has been given to ~2 billion people) which are transcribed into mRNA and then translated into the antigen, and selected live virus and virus-like particle vaccines will deemed genetic modifications as per official NIH policy. Simply put, including the “Can be transcribed or

translated" language as genetically modified is both scientifically wrong and irresponsible.

The dangers to public health and public trust by this inaccurate definition are enormous. It is easy to envision how anti-vaccine organizations can use this scientifically incorrect definition (which will become official NIH policy) to push regulators and policymakers to weaponize the policy and its enforcement mechanisms. Even if anti-vaxxers don't attack research institutions or universities, they will certainly use the new official NIH policy to falsely claim that vaccines are genetically modifying patients.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): My major concern is that this new policy will enshrine an incorrect (and dangerous) definition of genetic modification as official NIH policy. I have quoted the problematic language below:

Genetic modification:
• The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
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• Have the potential for one or more cycles of replication in a cell; or
• Can be transcribed or translated; or
• The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.

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3. Continued utility of Risk Groups: My major concern is that this new policy will enshrine an incorrect (and dangerous) definition of genetic modification as official NIH policy. I have quoted the problematic language below:

Genetic modification:
• The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
• Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
• Have the potential for one or more cycles of replication in a cell; or
• Can be transcribed or translated; or
• The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.

All prior definitions of genetic modification have centered on techniques and experiments that caused changes to the genomic DNA/RNA of the host cell, virus, or organism. However, as the text above shows, this proposed policy change ignores that decades-old scientific consensus. As the new language includes nucleic acids that "Can be transcribed or translated" this policy will incorrectly classify the vast majority of vaccine technologies as Genetic modification even though no vaccine platform alters the genome of the recipient.

For example, under this definition, all mRNA vaccines (whose sole function is to be translated into antigen protein that trains the immune system), all virally-vectored DNA vaccines (like the Oxford-AstraZeneca COVID-19 vaccine that has been given to ~2 billion people) which are transcribed into mRNA and then translated into the antigen, and selected live virus and virus-like particle vaccines will deemed genetic modifications as per official NIH policy. Simply put, including the "Can be transcribed or translated" language as genetically modified is both scientifically wrong and irresponsible.

The dangers to public health and public trust by this inaccurate definition are enormous. It is easy to envision how anti-vaccine organizations can use this scientifically incorrect definition (which will become official NIH policy) to push regulators and policymakers to weaponize the policy and its enforcement mechanisms. Even if anti-vaxxers don't attack research institutions or universities, they will certainly use the new official NIH policy to falsely claim that vaccines are genetically modifying patients.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): no comment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: templates are useful

6. Other feedback relevant to this resource: N/A

47. Ernesto Abel-Santos

I am responding: On behalf of myself

Name: Ernesto Abel-Santos

Name of Organization: Unlv

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/21/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious disease animal models

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: "Any incidents involving exposures at BSL-2/ABSL-2 that require agent-specific treatment beyond basic first aid..."

This sector is overkill. Exposures to BLS-2/ABSL-2 is normally followed by prophylactic treatment. Although technically not first-aid, these prophylactics are normally given out of excess caution and are not really disease related. These could be handled by the IBC alone

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

48. Douglas Brash

I am responding: On behalf of myself

Name: Douglas Brash

Name of Organization: Yale School of Medicine

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/21/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): cancer

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: It will be helpful to explicitly state the NIH definition of "biohazard" and also state what it is not.
"Biohazard" was originally roughly "a biological organism or material that is a hazard". Not, for example, an x-ray machine or an ultraviolet lamp. Over the years, NIH Study Section members have conflated "biohazard" with "hazard", ie, "anything that is hazardous to a biological organism like a human". This results in a series of inappropriate requirements and red tape affecting non-biological hazards.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The risks associated with specific biohazards seem the same across all localities, ie, reasonably definable at the federal level. So would the mitigation and oversight methods. The challenge instead lies in which level (local vs federal) has the expertise, manpower, and motivation to oversee. Corporations have well documented conflicts of interest.

3. Continued utility of Risk Groups: I don't have the expertise to advise on this point.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I don't have the expertise to advise on this point.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I have nothing to suggest on this point.

6. Other feedback relevant to this resource: Just that please don't make such resources a series of webpages containing URLs to other webpages, often containing conflicting information.

49. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/22/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: See attached.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: See attached.

Uploaded File: NIH_Biosafety_Draft_Public_Comment.pdf

Public Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Disclaimer

These comments are submitted in my individual capacity as a biosafety professional and reflect my personal views and professional experience. They do not necessarily represent the views, policies, or positions of my employer, affiliated institution, Institutional Biosafety Committee, or any other organization.

1. Scope of Biological Safety Officer Responsibilities

The draft policy appears to require the appointment of a Biological Safety Officer (BSO) only for institutions conducting Risk Group 3, Risk Group 4, or gene drive modified organism research. NIH should clarify whether duties traditionally associated with the BSO role, including laboratory inspections, compliance assessments, and other oversight activities, are intended to apply only to RG3/RG4 and gene drive research or to the institution's broader biohazards portfolio. Specifically, if an institution is not required to appoint a BSO because it does not conduct RG3/RG4 or gene drive research, it is unclear who is expected to perform functions such as laboratory inspections, biosafety compliance assessments, and other operational oversight activities that support IBC review and continuing oversight.

Without additional clarification, institutions may reach different interpretations regarding the applicability of BSO-related duties, resulting in inconsistent implementation across the research community.

2. Ability to Delegate BSO Responsibilities

The draft policy identifies responsibilities of the BSO but does not address whether those duties may be delegated to other appropriately qualified institutional personnel.

At many institutions, biosafety programs rely on teams of biosafety professionals, EHS personnel, subject matter experts, and laboratory compliance staff who collectively support inspections, training, risk assessments, incident investigations, and other programmatic functions under the direction of the BSO. Given the substantial expansion of policy scope and oversight obligations, it may not be practical or feasible for a single individual to personally perform all duties associated with the role.

Specifically, NIH should clarify whether:

- BSO responsibilities may be delegated to appropriately trained and qualified individuals operating under the authority of the BSO;
- Certain duties must be performed exclusively by the designated BSO; and
- Institutions may establish a biosafety program structure that distributes operational responsibilities among multiple personnel while retaining overall accountability within the designated BSO role.

Providing clear guidance on delegation would promote implementation consistency and better reflect how biosafety programs operate across diverse institutions.

3. Practical Implementation of Externally Administered IBCs

The draft policy contemplates externally administered IBCs while expanding IBC duties, including periodic review of approved research to ensure compliance.

Additional clarification would be helpful regarding how externally administered IBCs are expected to fulfill these ongoing compliance oversight responsibilities. Many of the responsibilities described in the draft policy, including periodic review of approved activities, assessment of institutional compliance, review of inspection findings, and evaluation of corrective actions, may require detailed knowledge of institutional facilities, personnel, training programs, and day-to-day operations.

Specifically, NIH should clarify:

- How externally administered IBCs are expected to conduct meaningful periodic reviews of approved research occurring at institutions where committee members may have limited visibility into local operations;
- Whether institutions utilizing external IBCs will be required to maintain local biosafety personnel or compliance programs to support these activities;
- How responsibilities will be divided between an external IBC and institutional officials responsible for implementing biosafety oversight programs; and
- What mechanisms NIH envisions to ensure consistency and accountability when ongoing compliance oversight responsibilities are shared between external committees and local institutional personnel.

Additional guidance in this area would help institutions determine whether external IBC models remain practical under the expanded oversight framework proposed in the draft policy.

4. Clarification of Public Posting and Incident Reporting Requirements

The draft policy expands incident reporting expectations and requires certain biosafety incidents to be reported to the IBC. However, it is unclear how the requirements for public disclosure and use of the NIH incident reporting template apply when an event is reportable to the IBC but does not meet the threshold for reporting to NIH.

Specifically, NIH should clarify:

- Whether incidents that require reporting only to the IBC must also be posted on the institution's publicly accessible website.
- Whether the standardized NIH incident reporting template is required for incidents that are reviewed solely by the IBC, or only for incidents that must be reported to NIH.
- Whether institutions may use their existing incident investigation and reporting mechanisms for IBC-only reportable events.

Additional clarification would promote consistency in institutional reporting practices and help ensure that public disclosure requirements are implemented as intended.

5. Clarification of Records Retention Requirements

The draft policy appears to link retention of biosafety oversight records to the retention period associated with the applicable funded research project. While NIH may intend to ensure that biosafety oversight records remain available throughout the lifecycle of supported research, additional clarification is needed regarding how institutions are expected to implement these requirements in practice.

Large research institutions frequently oversee numerous simultaneously active research projects involving multiple principal investigators, multiple funding sources, and varying grant periods. IBCs commonly review protocols, incidents, policy matters, and other agenda items that may affect multiple research projects during a single meeting. As a result, a single set of IBC meeting minutes may contain information relevant to numerous protocols and NIH awards with different project end dates and retention requirements.

Specifically, NIH should clarify:

- How institutions should determine the applicable retention period for meeting minutes and other records that pertain to multiple grants and investigators.
- Whether institutions are expected to associate individual portions of IBC records with specific awards.
- Whether a single retention period may be applied to institutional records that support multiple research projects.
- Why grant-specific retention requirements are necessary for institutional oversight records that may extend beyond any single funded project.

Several provisions of the draft policy significantly expand institutional oversight responsibilities while relying on institutional records that are frequently created and maintained at the committee or program level rather than at the grant level. NIH should consider providing additional implementation guidance to ensure that institutions can comply consistently and efficiently with the new requirements.

6. Clarification of NIH Determination of Minimum Biocontainment Levels

The draft policy states that IBCs are responsible for:

> "Petitioning NIH for determination of the minimum biocontainment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available in the BMBL. The IBC may not approve such research until authorized by NIH and any other applicable Federal, State, or local entities."

While this language clearly establishes a pathway for unresolved emerging, novel, or zoonotic agents, additional clarification is needed regarding biological agents that are not specifically addressed in the BMBL but are not determined by the IBC to be emerging, novel, or zoonotic agents.

Specifically, NIH should clarify:

- Whether NIH review is required whenever an agent is not listed in the BMBL, regardless of whether it is considered emerging, novel, or zoonotic.
- Whether IBCs may independently determine an appropriate containment level using available scientific literature, agent characteristics, risk assessment principles, and other authoritative guidance when the agent is not addressed in the BMBL.
- What criteria should be used to determine whether an agent is sufficiently "novel," "emerging," or "zoonotic" to require NIH consultation.
- Whether NIH intends to develop a formal process and timeline for responding to institution requests for containment determinations.
- Whether NIH containment determinations will continue to be issued on a protocol-specific basis for individual principal investigators and institutions, similar to the current process, or whether NIH intends to publicly post containment determinations that may be relied upon by other institutions conducting substantially similar research.
- If containment determinations will be made publicly available, whether institutions may rely on previously issued NIH determinations when conducting local risk assessments and protocol reviews without submitting a new request to NIH.
- Whether NIH intends to create a centralized repository, database, or other publicly accessible resource for containment-level determinations to promote national consistency in biosafety oversight.

Without additional clarification, institutions may arrive at differing interpretations of when NIH consultation is required. Some institutions may petition NIH for all biological agents not explicitly listed in the BMBL, while others may rely on institutional risk assessment processes. Similarly, it is unclear whether containment determinations will remain institution- and project-specific or whether NIH intends to establish publicly available precedent that can be used across the research community. Additional guidance in this area

would improve consistency, transparency, and efficiency while reducing duplicative review efforts for similar research activities.

7. Clarification Regarding Removal of Previously Exempt Activities

The draft policy appears to eliminate several exemptions that have historically existed under the NIH Guidelines, including certain activities involving well-characterized laboratory strains and routine activities involving established transgenic rodents.

Because these activities are commonplace at many research institutions and have historically been considered low risk, additional clarification regarding the rationale for removing these exemptions would be helpful.

Specifically, NIH should clarify:

- What biosafety concerns or oversight gaps prompted the removal of exemptions previously provided under the NIH Guidelines.
- Whether NIH has evaluated the anticipated increase in IBC workload resulting from review of activities that were previously exempt.
- Whether NIH intends to establish streamlined review mechanisms or administrative review pathways for activities that are widely regarded as low risk.
- Whether institutions retain discretion to implement abbreviated review processes for low-risk activities that no longer qualify for exemption under the proposed policy.
- How NIH expects institutions to allocate resources to accommodate the anticipated increase in protocol submissions and continuing oversight obligations.

Given the substantial expansion of the policy's scope, additional information regarding the rationale for removal of longstanding exemptions and the expected implementation approach would assist institutions in planning for compliance and resource allocation.

8. Clarification Regarding Delegated Review Authority

The draft policy permits review of certain low-risk activities through delegated review conducted by an individual or subgroup of IBC members. Additional clarification regarding the qualifications and authority of individuals performing delegated reviews would promote consistent implementation across institutions.

Specifically, NIH should clarify:

- Whether delegated review conducted by an individual must be performed by a current member of the IBC.
- If delegated review must be conducted by an IBC member, whether that individual must be a voting member of the committee.
- Whether alternate members may conduct delegated reviews.

- Whether subject matter experts, biosafety professionals, or other institutional personnel who are not appointed IBC members may perform delegated reviews when authorized by the institution.
- Whether delegated reviewers must report review outcomes to the convened IBC and, if so, what documentation requirements NIH expects institutions to maintain.
- Whether NIH intends delegated review to function similarly to designated member review processes used by Institutional Review Boards or whether a distinct process is envisioned for IBC oversight.

Additional guidance regarding delegated review authority would help institutions establish efficient review processes while ensuring that oversight remains consistent with NIH's expectations.

9. Implementation Timeline

The draft policy represents a substantial expansion of institutional biosafety oversight responsibilities and may require significant operational, administrative, and financial investments by regulated institutions.

Many of the proposed requirements will likely necessitate changes to institutional infrastructure, including modification of IBC procedures, development of new compliance and recordkeeping processes, expansion of biosafety program staffing, recruitment of additional subject matter expertise, implementation of new training programs, and updates to institutional policies and guidance documents.

As a result, the proposed six-month implementation period following publication of the final policy may not provide sufficient time for institutions to achieve full compliance, particularly for large research organizations with extensive research portfolios.

NIH should consider providing a minimum implementation period of twelve months following publication of the final policy. A longer implementation timeline would allow institutions to:

- Conduct gap assessments and develop implementation plans.
- Secure necessary budgetary and personnel resources.
- Recruit and train additional biosafety and compliance staff, where needed.
- Update institutional policies, procedures, and information systems.
- Modify IBC review processes and committee structures.
- Educate investigators and research personnel regarding new requirements.
- Establish compliance programs capable of meeting the expanded expectations of the policy.

Providing at least one year for implementation would improve consistency across institutions and support successful adoption of the policy while advancing NIH's biosafety objectives.

Conclusion

The draft policy frequently establishes new institutional responsibilities but does not always specify the operational processes by which those responsibilities should be implemented. Clarification regarding the scope of BSO duties, delegation of responsibilities, oversight by externally administered IBCs, incident reporting and public disclosure requirements, records retention expectations, NIH review of novel biological agents, removal of longstanding exemptions, and delegated review authority would improve consistency and facilitate implementation across the research community. In addition, the substantial expansion of institutional responsibilities warrants a longer implementation period than the six months currently proposed. Additional implementation guidance, decision trees, examples, clearly defined processes, and a minimum one-year implementation timeline would help institutions comply with the policy in a consistent and efficient manner while advancing NIH's goals of transparency, accountability, and biosafety.

50. Michael Eichner

I am responding: On behalf of myself

Name: Michael Eichner

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 9/22/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: support NIH's objective of modernizing and strengthening biosafety oversight and agree that biosafety requirements should evolve as scientific capabilities and risks evolve. However, I have significant concerns about the proposed expansion of the policy to encompass all genetically modified organisms, including routine genetically modified laboratory mice.

The proposed definition of research involving biohazards includes “cells, viruses, or organisms, other than plants, that have been genetically modified.” Under the proposed policy, research conducted with transgenic organisms at BSL-1/ABSL-1 would require review and approval by an individual or subgroup of IBC members before initiation.

This represents a substantial expansion of IBC oversight for genetically modified laboratory animals. Importantly, the presence of a genetic modification alone is not necessarily an appropriate proxy for biosafety risk.

Genetically modified mice encompass an extraordinarily broad range of research tools, including conventional transgenic animals, knockout and knock-in models, conditional alleles, Cre-driver lines, reporter strains, humanized models, and CRISPR-generated models. Many of these animals are well characterized and pose no meaningful biosafety risk beyond that associated with conventional laboratory mice.

I therefore recommend that NIH revise the scope of the policy so that the mere presence of a transgene or other genetic modification does not automatically trigger IBC registration and approval.

Instead, IBC oversight should be triggered when the genetic modification or proposed experimental use creates a credible biosafety, environmental, or biosecurity risk that warrants IBC expertise.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed policy appropriately recognizes that oversight should be proportional to risk. However, I am concerned that the

proposed treatment of genetically modified mice does not achieve that objective.

The draft places transgenic organisms maintained at BSL-1/ABSL-1 into a category requiring review and approval before initiation, albeit through delegated review by an individual or subgroup of IBC members.

While delegated review may reduce the burden associated with full-committee review, it does not eliminate the fundamental administrative problem. Registration, submission, review, approval, documentation, tracking, renewal, and amendment of thousands of routine mouse lines would still create a substantial institutional workload.

Moreover, the draft requires approval for a period of no more than three years, after which a new de novo registration and review would be required. Changes that could affect the original biosafety assessment would also require review and approval before the research proceeds.

For institutions with large biomedical research programs, this could translate into thousands of IBC registrations and subsequent administrative actions associated with genetically modified mouse research.

The resulting workload would not be trivial. It would require substantial effort from:

Principal investigators and laboratory personnel;
IBC coordinators and biosafety personnel;
IBC members and delegated reviewers;
Comparative medicine and veterinary personnel;
Animal facility personnel; and
Institutional administrative and compliance offices.

This workload would exist even when the underlying genetic modification presents no meaningful biosafety concern.

3. Continued utility of Risk Groups: A central principle of the proposed policy is that biosafety oversight should be calibrated to risk. I strongly support this principle and believe it should be applied more explicitly to routine genetically modified laboratory animals.

A transgene should not, by itself, be considered sufficient evidence of a biosafety risk requiring IBC approval.

For example, a mouse carrying a fluorescent reporter, tissue-specific Cre allele, conventional knockout, loss-of-function mutation, or well-characterized disease-associated knock-in is fundamentally different from an organism engineered to possess characteristics that could increase pathogenicity, transmissibility, host range, environmental persistence, or other meaningful biosafety risks.

The draft policy itself describes risk assessment as considering the characteristics of the biohazard, the manipulations being performed, and any genetic modifications. This risk-based approach should be used to distinguish routine genetically modified laboratory animals from organisms for which the genetic

modification itself creates a meaningful biosafety concern.

I recommend that NIH establish an explicit exemption or streamlined institutional determination for genetically modified laboratory mice when:

the animals are maintained at BSL-1/ABSL-1;
the genetic modification is well characterized;
the modification does not introduce a human or animal pathogen or toxin;
the modification does not create or substantially increase pathogenicity, transmissibility, environmental persistence, or host range;
there is no reasonable expectation of a significant environmental consequence from accidental release; and
the animals remain subject to applicable institutional animal-care, veterinary, and occupational-health oversight.

Such research could be documented through an institutional screening or self-determination process without requiring individual IBC registration and approval for each mouse line.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The potential administrative burden deserves particular attention.

Laboratory mice are one of the most widely used experimental organisms in biomedical research, and genetically modified mouse lines are routinely generated as part of basic and translational research. A single research program may generate multiple new lines in a year, while large biomedical research institutions may maintain thousands of genetically modified lines.

Requiring IBC registration of these animals would therefore create a volume of submissions that is fundamentally different from the type of research traditionally requiring intensive biosafety review.

Even if each individual submission required only a modest amount of staff and reviewer time, the aggregate burden could be substantial.

For example, if an institution generated or maintained several thousand qualifying mouse lines and each registration required only 30 minutes of combined investigator, administrative, and reviewer time, the resulting workload would already represent well over 1,000 hours of institutional effort. A three-year renewal cycle and amendments would create a continuing workload rather than a one-time implementation burden.

This raises an important question of resource allocation: Is the scientific value of requiring IBC review for every routine genetically modified mouse proportionate to the biosafety risk being addressed?

In my view, the resources of IBCs would be better directed toward research involving pathogens, toxins, novel organisms, gene-drive systems, altered host range, increased pathogenicity or transmissibility, and other activities for which specialized biosafety expertise is essential.

NIH itself identifies streamlining administrative burden as an objective of its proposed risk-based oversight framework. Routine genetically modified mouse research presents an important opportunity to achieve that objective.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Administrative Burden on IBCs

The potential administrative burden deserves particular attention.

Laboratory mice are one of the most widely used experimental organisms in biomedical research, and genetically modified mouse lines are routinely generated as part of basic and translational research. A single research program may generate multiple new lines in a year, while large biomedical research institutions may maintain thousands of genetically modified lines.

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NIH itself identifies streamlining administrative burden as an objective of its proposed risk-based oversight framework. Routine genetically modified mouse research presents an important opportunity to achieve that objective.

Impact on Biomedical Research and Scientific Progress

The administrative burden would also extend beyond the IBC.

Modern biomedical research increasingly relies on rapid generation and evaluation of genetically modified mouse models. Investigators frequently create new models in response to experimental

findings, modify existing models to answer follow-up questions, or generate multiple related lines to establish causality.

This iterative process is particularly important for disease-discovery research.

For example, an investigator may identify a candidate disease-associated gene, generate a knockout or knock-in model, observe a phenotype, and then generate a tissue-specific or inducible version of the model to determine where and when the gene functions. Each subsequent model can be essential to interpreting the preceding experiment.

Adding a separate biosafety registration and approval process to each of these steps could introduce delays into an inherently iterative scientific process.

The cumulative effect could be significant: researchers may generate fewer models, delay experiments, or avoid exploratory lines of investigation because the administrative process required to initiate the work becomes disproportionate to the biosafety risk.

This is particularly concerning for research into diseases for which the underlying biological mechanisms remain poorly understood. Genetically modified mouse models are often essential to identifying disease mechanisms, validating therapeutic targets, and determining whether findings from cellular or computational systems translate into an intact organism.

Accordingly, the proposed requirement could unintentionally stymie scientific progress in disease discovery while providing little corresponding increase in biosafety protection for routine, well-characterized mouse models.

Relationship to Existing Animal Research Oversight

Genetically modified mouse research already occurs within a substantial framework of institutional oversight.

Investigators using these animals are subject to IACUC review and oversight, veterinary supervision, animal facility requirements, occupational-health programs, institutional policies, and established procedures for the generation, importation, transfer, housing, and use of genetically modified animals.

The draft policy appropriately recognizes the IBC, IRB, and IACUC as three foundational pillars of institutional oversight.

Rather than creating a duplicative approval process for routine genetically modified mice, NIH should consider how these existing oversight mechanisms can be leveraged to identify the relatively small subset of genetically modified animals that present meaningful biosafety concerns.

A risk-based screening mechanism could allow animal-care and biosafety professionals to identify circumstances requiring IBC review without requiring the IBC to formally register every genetically

modified mouse line.

NIH's effort to modernize biosafety oversight is important, and a stronger risk-based framework has the potential to improve biosafety while reducing unnecessary administrative requirements.

However, requiring IBC registration and approval of essentially every genetically modified mouse would create a large and continuing administrative burden for investigators, IBCs, biosafety programs, and animal research programs.

More importantly, the volume of routine mouse genetics that would enter the IBC system could overwhelm institutional biosafety resources and divert IBC attention away from research involving genuinely significant biosafety risks.

The proposed policy should therefore distinguish genetic modification from biosafety risk. A transgene should not automatically trigger IBC review.

NIH should establish a clear exemption or streamlined institutional determination process for conventional, well-characterized genetically modified laboratory mice maintained under BSL-1/ABSL-1 conditions. This would be more consistent with the stated objective of risk-calibrated oversight and administrative streamlining while preserving rigorous IBC review for genetically modified organisms that present meaningful biosafety, environmental, or biosecurity concerns.

The objective should not be to review every genetically modified organism. The objective should be to ensure that organisms presenting meaningful risk receive appropriate review.

That distinction is essential if NIH is to strengthen biosafety oversight without creating an administrative bottleneck that could impede the generation and use of the animal models that are fundamental to modern biomedical research.

51. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/22/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed scope is overly broad and would significantly expand NIH oversight beyond its traditional role. The policy would apply not only to NIH-funded research but also to non-NIH-funded research conducted at institutions that receive NIH funding. This expansion is not adequately justified and could have substantial unintended consequences for academic research institutions.

The scope also captures many low-risk and well-characterized experimental systems, including common genetically modified cells and organisms that have long histories of safe use. Inclusion of these activities may substantially increase administrative burden without providing measurable improvements in biosafety.

NIH should narrow the scope to focus on activities that present demonstrably elevated risk to laboratory personnel, public health, or the environment. Explicit exemptions should be created for established low-risk research platforms.

In addition, the public disclosure requirements associated with IBC review create concerns regarding protection of intellectual property, especially for early-stage discoveries that may ultimately become patentable inventions. Universities and investigators may be forced to file patents prematurely or alter research-development timelines to protect intellectual property.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): While risk-based oversight is an appropriate goal, the proposed oversight structure may not achieve meaningful risk stratification in practice because too many activities fall within the review framework.

A policy cannot be considered fully risk-based if low-risk and high-risk activities are both subjected to extensive documentation and review requirements. Many routine laboratory activities may become subject to additional administrative processes despite decades of safe use.

The proposed framework may also create substantial review bottlenecks at institutional IBCs. Large

research institutions could experience significant increases in protocol submissions, amendment requests, periodic reviews, and documentation requirements.

NIH should further reduce oversight requirements for low-risk activities and reserve the most intensive review structures for genuinely novel, uncertain, or high-consequence research.

The policy should also undergo pilot implementation at selected institutions before nationwide deployment to better understand resource and workload implications.

3. Continued utility of Risk Groups: Risk Groups and Biosafety Levels address different aspects of biosafety and should continue to be used as complementary tools.

Risk Groups provide critical information regarding the inherent biological characteristics of an agent, while Biosafety Levels reflect the appropriate containment requirements for specific experiments. Neither system should replace the other.

The draft appropriately recognizes that Risk Groups and Biosafety Levels are not equivalent. However, NIH should avoid creating requirements that could lead reviewers to rely excessively on rigid classifications rather than experiment-specific scientific risk assessment.

Particularly for modern technologies such as gene editing, synthetic biology, viral vectors, and attenuated constructs, professional scientific judgment remains essential. The final policy should preserve flexibility for investigators and IBCs to conduct case-specific assessments.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The enforcement provisions are concerning because they are linked to a policy that contains numerous areas requiring subjective interpretation.

The draft indicates that noncompliance may lead to additional award conditions, funding consequences, or other enforcement actions. Such provisions are appropriate for serious violations but may be excessive when applied to good-faith disagreements regarding risk classification, reporting thresholds, or oversight requirements.

NIH should distinguish clearly between:
• Serious biosafety violations that create genuine risk.
• Administrative or procedural errors.
• Good-faith differences in scientific judgment.

The incident-reporting requirements are also likely to encourage defensive overreporting. Institutions may report large numbers of low-risk events simply to avoid potential enforcement actions.

The policy should include:
• Clear reporting thresholds.
• Safe-harbor protections for voluntary reporting.
• Opportunities for corrective action before sanctions.

• Formal appeal mechanisms.
• Proportional enforcement standards.

Most importantly, public posting of institutional incident reports should not be required. Transparency can be achieved through NIH-generated national summaries that are de-identified and focused on lessons learned rather than institution-specific disclosures.

From an innovation perspective, the proposed requirement for public posting of IBC meeting minutes and incident reports presents substantial intellectual property concerns. Biosafety reviews frequently occur during the earliest stages of technology development, before patent applications have been filed. Even with redaction, mandatory public disclosure creates a risk of revealing commercially valuable scientific information, undermining patent protection, reducing industry engagement, and discouraging open discussion during biosafety review. NIH should replace institution-specific public posting requirements with de-identified national reporting of biosafety trends and incidents.

From a university PI perspective, the public-posting requirement is probably the aspect of this policy most likely to draw opposition from technology transfer offices, research universities, biotech companies, and academic inventors. The biosafety provisions themselves are unlikely to affect patents directly; the transparency and disclosure provisions could.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The NIH should require public reporting only of IBC decisions and biosafety determinations, not detailed meeting discussions. Detailed scientific deliberations should remain confidential institutional records to protect intellectual property, facilitate open discussion, and minimize unnecessary administrative burden.

1. Minutes should document decisions, not detailed scientific discussions

IBC minutes should record:

Attendance
Actions taken
Voting outcomes
Risk-assessment conclusions
Required containment levels

They should not require detailed descriptions of scientific methods, experimental constructs, unpublished technologies, or research strategies.

2. Intellectual property protection is a major concern

Many projects reviewed by IBCs involve early-stage discoveries that have not yet been patented.

Broad publication of meeting minutes could:

Undermine patent protection

Reveal competitive research directions
Complicate technology-transfer efforts
Discourage industry collaborations

NIH should explicitly allow omission of scientific details that are not essential for public understanding of biosafety decisions.

3. Public posting requirements create major administrative burden

The requirement to review, redact, approve, and post minutes may require substantial involvement from:

Biosafety offices
Institutional legal counsel
Compliance offices
Technology-transfer offices

This administrative burden is unlikely to improve biosafety.

4. Minutes should use standardized decision summaries

Rather than publishing extensive meeting notes, NIH should consider a standardized summary format:

Project category
Risk level
Containment level
Approval status
Special conditions

This would improve consistency and transparency while reducing disclosure concerns.

5. Public availability may inhibit open scientific discussion

Investigators and IBC members may be less willing to engage in candid discussion if comments could ultimately become publicly available.

Effective biosafety oversight relies on:

Open questioning
Honest discussion of uncertainties
Critical evaluation of proposed experiments

The meeting-minutes template should be structured to preserve this environment.

6. Other feedback relevant to this resource: The draft significantly underestimates the resources required for implementation.

Successful implementation will require:

• Additional biosafety personnel.
• Expanded IBC administrative support.
• Investigator training programs.
• Information technology infrastructure.
• Legal review of public disclosures.
• Processes for protection of confidential and proprietary information.

These requirements constitute a substantial unfunded mandate for research institutions.

The proposed six-month implementation period is unrealistic. Institutions will need considerably more time to:

• Revise policies and procedures.
• Train investigators and staff.
• Expand IBC membership and expertise.
• Review existing protocols.
• Develop systems for reporting and public disclosure.

NIH should provide:

• Standardized templates.
• Sample risk-assessment tools.
• Detailed implementation guidance.
• Decision trees for incident reporting.
• Frequently asked questions.
• Additional funding support.
• A phased implementation schedule extending beyond six months.

A revised draft should be released for an additional round of public comment before final implementation due to the magnitude of the proposed changes.

52. Newt Hilliard

I am responding: On behalf of myself

Name: Newt Hilliard

Name of Organization: Arkansas Tech University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/22/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: n/a

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Calibration of oversight to risk seems appropriate to the level of proposed research. Our current Institutional Biosafety Committee (IBC) is composed of both faculty, a community health care professional and a community engineering professional. All members have training and experience in working in environments with vary levels of risk. They are all aware of risk mitigation practices/procedures.

3. Continued utility of Risk Groups: Biosafety Levels have worked well for us since we do not currently have, nor do we plan to have, any research involving hazards above BSL2. This includes the growth of BSL2 level microorganisms for the purpose of isolating gDNA and cloning/expression of genes for non-toxic proteins in BSL1 level expression vectors. We might also perform limited growth of the BSL2 microorganisms for proteomics type analysis.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): n/a

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Since our IBC is relatively new, templates for both Incident reporting and Meeting Minutes are greatly appreciated.

6. Other feedback relevant to this resource: Again, our IBC is relatively new. We would appreciate any guidance available.

53. Lauren Walker

I am responding: On behalf of myself

Name: Lauren Walker

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am concerned that the proposed changes would significantly increase administrative burden and slow biomedical research. The expanded NIH oversight raises important questions about implementation: Who will be responsible for enforcing these requirements, and will additional personnel and funding be needed? What will the costs be to NIH and research institutions? While appropriate biosafety oversight is essential, the benefits of these additional requirements should be weighed against their potential to create delays, increase costs, and add unnecessary bureaucracy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

54. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Government Agency

Role: Government Official

Date Submitted: 9/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope should be expanded to include the recent USG Policy related to potential gain of function research. An agent that does not currently cause human disease could be used in a protocol that has the potential for gain of function. This could be revised to say "potential to cause human disease"

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A voting member recused from voting should not count towards quorum. The IBC should have the same regulations as all of the other committees when it comes to quorums and recusals.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Reporting to NIH within 24 hours seems unreasonable, particularly since NIH does not typically respond that quickly and is not available 24/7.
Posting minor incidents that the IBC handles on the public facing website seem excessive. the minutes will already be available so the information can be obtained if someone really wants it but it isn't as accessible for smaller incidents like minor mouse bite.

the IBC minutes meeting template is excessive regulatory burden that will cost every institution time, money, and overregulation. Requiring specific information be included seems more doable. With most facilities using electronic protocol management systems, many will not be able to shift to this specific format but adding details to the minutes is much easier. I see no reason for a specific required minutes template in this day of electronic software systems.

6. Other feedback relevant to this resource: This policy is very vague and while some leeway should be provided, it lacks a lot of detail that could prove difficult in the future. Examples:
-More details should be provided for the delegated member review-Is the Individual an IBC member?

What is a minor amendment?
-Risk assessments- prior to initiating research involving biohazards- Biohazards is not defined but does this mean only those reviewed by the IBC? Should the IBC review assessments from all biohazards, not just those that cause human disease?
-BSO- the duties are for the BSL3/4/GDMO work only? this should be changed to all facilities working with biological agents covered under this policy. Using biological agents that could cause human disease should come with a biosafety professional appointment. The entire BSO section is confusing. Does the last sentence for an institution without a BSO must designate someone with these responsibilities mean only the institutions required to have a BSO or those that aren't required to have a BSO still must assign these bulleted duties to someone else? This could be outlined much better to make this clear.
Training- while this remains the same from NIH Guidelines, a more specific timeframe or training outline should be provided. Requiring training every 3 years in coordination with the de novo approval would make sense.
-The IBC is given more responsibilities and options to make it more equal with the IACUC and IRB. however, there is no mechanism for protecting this authority. There should be ability for IBC to stop work, remove approval, etc. similar to the IACUC.
-Assurance- a lot more information will be required for this- how will NIH process all of these assurances initially? What should be included?
Implementation should be more than a year.

55. anon

I am responding: On behalf of myself

Name: anon

Name of Organization: n/a

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 9/24/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft policy will be a legacy of ineptitude by those who put it forth.
Delete the draft policy and start from the NIH Guidelines that have been developed for ~50 years.
Take into consideration the feedback NIH received by geographical area.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): RG2/BSL2 research is delegated review, whereas formerly exempt RG1/BSL1 research now requires registration and review... more paperwork for BSL1, fewer eyes on BSL2.
That is the exact opposite of tiering oversight and calibration to risk.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Empowering IBCs does not mean micromanaging by issuing and requiring a template for minutes.

6. Other feedback relevant to this resource: N/A

56. New England Society for Biomedical Research

I am responding: On behalf of an organization

Name: Aimee Christian, Ph.D.

Name of Organization: New England Society for Biomedical Research

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 9/27/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical research that involves animal research or New Approach Methodologies (NAMs)

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached

3. Continued utility of Risk Groups: See attached

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attached

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached

6. Other feedback relevant to this resource: See attached

57. EKG Global Solutions, LLC

I am responding: On behalf of an organization

Name: Eric Griffin

Name of Organization: EKG Global Solutions, LLC

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Member of the Public

Date Submitted: 9/27/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The following relates to inadvertent gaps specifically within Section V-D. Requirements and Considerations for Risk Assessment of Manipulations of Biohazards.

AI-driven robotic labs have been discussed at length in the literature as a potential AI-enhanced biological risk as being capable of removing the human link to whistleblow on inappropriate research or protocols. I believe it would be prudent to include risk management principles within the section mentioned above or another appropriate section to preclude NIH awards to develop autonomous laboratory technology or use of autonomous laboratory technology when conducting NIH funded research without having constant direct human oversight. Said human oversight needs to be conducted by personnel who are appropriately trained to continually monitor the processes used by the AI agent(s) for risks while the research is conducted.

The following relates to the section: Section III-D. Responsibilities of the National Institutes of Health (NIH)

The NIH should work with all appropriate parties to develop a very simple emergency notification flowchart for each IBC to adopt and reference this within the draft incident reporting form. I know existing IBCs or similar institution research oversight bodies have reporting requirements but technology continues to develop faster than regulations. I believe having a standard call down emergency notification form for the initial minutes to an hour after awareness of an incident that could create public exposure is critical to provide any opportunity to contain further public risk. The notification flow chart should include all response organizations that have the personnel with knowledge, training, and readily available resources to respond immediately. This may include state and federal assistance. Further, NIH funding agreements should include language that prohibits institutions from delaying notification for the purpose of engaging in legal risk mitigation or reputation management activities prior to notification.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Federal for policy and NIH award stipulations. Institution level for implementing the policy.

3. Continued utility of Risk Groups: Risk groups are essential but evaluation of scope overlap or conflicting policies should occur with any NIH policy modifications.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Consider a public facing website that lists institutions that have signed a voluntary agreement to abide by NIH policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Related to section 1, the incident reporting template should be modified to state that completion of the form should occur after all immediate emergency notifications are made.

6. Other feedback relevant to this resource: I have nothing to add that is not stated above. Thank you for the opportunity to provide feedback.

58. Jeffrey M. Bell

I am responding: On behalf of myself

Name: Jeffrey M. Bell

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy should cover all work that can increase a pathogen's transmissibility or virulence in humans, not only recombinant nucleic acids. Gaps: privately funded work at NIH-funded institutions; agent transport; information and AI tools that lower the barrier to the same experiments. "Biohazard" that stops at current Risk Group lists will miss enhanced agents. A companion memo (attached) states the public-health case.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): High-consequence and genetically enhanced work needs federal review that the performing lab does not control. Local IBCs are necessary and not sufficient when the institution's funding depends on the project. Calibration to risk is right; "streamlining" must not mean the lab grades its own exam.

3. Continued utility of Risk Groups: Risk Group of the starting agent is a poor baseline once the agent is modified. Containment should follow the modified phenotype and BMBL BSL, with an explicit up-classification trigger when transmissibility or immune evasion is increased.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Policy without audit and a funding consequence is a guideline. NIH should be able to pause awards for unreported incidents and for work that matches a banned enhancement category. Voluntary compliance at non-NIH sites is not a substitute for a statutory floor.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Require a public, timely incident report: agent, enhancement status, BSL, whether NIH-funded, date, and whether IBC reviewed. Minutes should record dissent and the risk rationale, not only the vote.

6. Other feedback relevant to this resource: NIH should publish a one-page definition of prohibited enhancement, a decision tree for IBC up-classification, and a dual-use / AI-assisted experiment flag. Guidance that only restates BMBL will not close the gap.

Uploaded File: Zero-Pandemic.pdf

Description: Supplement to comments on Draft NIH Biosafety Policy: Zero Pandemic Initiative memo (definitions, independent oversight, enhancement research). Jeffrey M. Bell, individual, 28 Sept 2026.

Submitted as supplement to comments on Draft NIH Biosafety Policy, September 28, 2026. Jeffrey M. Bell, individual.

Full recommendation memo

1. Opening statement

High-containment laboratories are expanding rapidly around the world. Strong, consistent safety standards are essential to prevent laboratory accidents and reduce biosecurity risks.

That sentence names the documented problem (accidents and weak, uneven standards) and stays precise about the speculative piece (whether any given pandemic was caused by a laboratory). The policy is powerful because it holds up either way.

2. Keep two problems apart

The real argument — we need better standards, oversight, and facility design globally — works whether COVID was natural, lab-related, or something else. Do not hang the legal or diplomatic case on proving a lab origin. That is what makes the package defensible.

A public debate on why expert and public views of origins have diverged can still be hosted (conferences, the public database). It is a process track, not the legal trigger.

3. The goal: zero pandemics

Two categories, and only two:

1. Stopping creation — end dangerous gain-of-function research.

2. Stopping leaks — even if a pathogen were created, it cannot leave the lab.

Everything else in this sheet is how to get from the present “Wild West” (few standards, little public awareness of the danger of the technology) to that end state.

Pandemics are more than mortality rates. They wreck economies, overwhelm hospitals, spike mental-health harm, and disrupt education and daily life for years. Harm is often invisible in headlines — a fisherman’s livelihood, a family’s years of loss, millions of stories that never led the news. COVID caused an estimated 7+ million confirmed deaths globally, with excess-mortality estimates running higher, regardless of origin theory. We owe those who suffered through no fault of their own a multi-generational solution so this does not happen again.

If the United States had any role in COVID, that is an additional moral reason to lead. It is not the proof of the policy.

4. How to talk about this (sequence)

TBD

5. Pillar A — Stop creation

5.1 Immediate: existing executive policy

Under current White House policy:

• Agencies are banned from funding dangerous gain-of-function (DGoF) studies.

• Agencies do not decide whether an experiment is DGoF. The independent ITPRB (Independent Technical and Policy Review Board, or the successor independent review body designated in the policy) makes that classification.

Keep that structure. Do not let funding agencies grade their own homework.

5.2 Next: statute with real criminal liability

The executive order is the start, not the finish. Congress should pass long-term law that:

- Prohibits dangerous gain-of-function work, not merely defunds it.
- Makes surreptitious DGoF a prosecutable offense with real jail time.
- Closes the gap between “we will not pay for it” and “you may not do it in secret.”

The public message and the statute should match: this used to be tolerated; it is now a crime.

5.3 Why criminal law is part of safety, not only of politics

Published sequence data, commercial synthesis with legitimate research and pharmaceutical uses, and widely taught laboratory skills mean the barrier to misuse is getting lower, not higher. Policy cannot un-publish sequences or realistically shut off all synthesis. It can control facilities, personnel, funding, and covert work. Assuming there are no bad actors is naive. Jail for covert DGoF, access control, and tech-transfer limits are the intervention points that remain.

(This memo does not discuss methods of synthesis or misuse. It addresses only where law and institutions can intervene.)

6. Pillar B — Stop leaks: robotics-only laboratories

Human presence in high-risk workspaces is the long-run failure mode. Documented incident history is dominated by procedural error (see §9). The only multi-generational solution that matches that fact is:

Transition all future high-containment capacity to robotics-only labs.

If a dangerous agent exists, it still should not be able to leave through a torn suit, a missed step, or a tired technician.

Do not expand conventional labs now. Facilities built on today's human-staffed model will be obsolete once robotics takes over. Building more of them is waste.

A 2–4× construction-cost premium for safer, standardized, or robotic facilities is a rounding error against pandemic-scale downside. Societies already accept airport-level security to prevent thousands of deaths per incident. A lab-originated pandemic could kill millions. In expected-value terms, the premium is not the hard part of the argument.

7. Moratorium on traditional BSL-3/4 construction

Until robotic designs are standardized (on a 5–10 year planning horizon):

• Pause new traditional BSL-3/4 construction.

• Allow replacement only under the standardized interim design in §8, on a case-by-case basis, not as a new wave of conventional capacity.

Why this is a strong, defensible position:

1. Sunk cost. Nations spending hundreds of millions on facilities that robotics will obsolete is a real, countable waste.

2. Proliferation. A moratorium stops the growth of BSL-3/4 labs worldwide. That is risk reduction even if nothing else changes.

3. Rhetoric. "We should wait for the better standard" is pragmatic. "We should pause because of biosecurity fear" is easier to dismiss. Use the first framing.

This is also the diplomatic clock: every conventional lab poured in concrete now makes later coordination harder.

8. Interim period — before robotics is ready

Robotics is the destination. The country is in a vulnerable window before it arrives. Another pandemic in that window could set the work back for years. Assume the worst and prioritize getting the interim system in place now.

8.1 Interim facilities

1. Update current lab standards so they are more detailed and stricter. Keep them non-mandatory at first, while the new baseline is socialized and inspected.

2. Create one standardized interim lab design (not robotic yet). Use it to replace existing labs case by case.

Public security rises. Long-run cost falls versus each lab inventing its own standards.

8.2 Interim governance (human error and conflicts of interest)

1. NIH cash awards for whistleblowers who report dangerous practices. This is a named, non-negotiable item. It addresses the massive imbalance between insiders who see risk and a system that punishes them for speaking.

2. Revolving-door ban. Officials at HHS, CDC, and NIH may not be hired by pharmaceutical companies after leaving office. Make that illegal. Post-government employment otherwise shapes behavior while in office.

3. Public experiment database with three functions:

- report experiment types;
- rate dangerousness;
- host a debate section (pros and cons).

4. Facility access control. Personnel screening, training, and background checks before work with high-risk (including RG4) agents are a neglected gap. Standards vary widely around the world. Policy should specify who gets in, and with what. This is one of the few choke points that remains after sequences and synthesis tools are already in the world.

5. Mandatory, transparent incident investigation. About 9% of lab incident reports (1900–2025) list unknown or unclear causes. That usually reflects reporting gaps, not true mysteries. A facility that had an accident and covered it up or failed to investigate still appears as “unknown cause” — a blank, not “deliberately hidden.” Better reporting systems are better safety practices. Sunlight is the best disinfectant.

8.3 New lab-safety division

Stand up a lab safety division with a public-facing mandate: standards, incident transparency, database, whistleblower intake, and support to ITPRB classification.

Tooling preference recorded from source notes: standardize analytical support on Grok, on the claim that it is more truth-seeking than other systems. Treat that as an administration tooling choice to be justified in procurement, not as a scientific finding.

8.4 Who sits at the table

Faith-based groups already have a seat in this administration. Include one or more faith-based members in the gain-of-function and lab-safety debate. This is a legitimacy and values question as well as a technical one.

9. Evidence to put in front of the public

Verify and footnote before use. Figures below are compiled from the source notes, not independently audited in this draft.

1. How often lab incidents happen. Most people assume accidents are rare. Source notes cite 1,126+ documented incidents over 125 years, 81 fatalities in recent decades, and procedural errors in nearly 70% of incidents. That last number is the engineering case for robotics-only labs.

2. Global oversight gaps. Source notes cite 91.6% of countries with BSL-3 labs lacking dual-use oversight. Frame as a coordination problem, not a blame campaign. It is alarming and nonpartisan.

3. Who gets access. Ask a concrete question: What vetting does a technician undergo before working with RG4 pathogens? Standards vary widely. This is personal and easy to understand.

4. Named incidents stick. Use specific near-misses and breaches, not only totals. Source notes cite a Fort Detrick 2025 halt after protective-suit damage. Confirm the official record before using the example.

5. Unknown cause ≠ mystery. Source notes cite ~9% of cases (1900–2025) with unknown or unclear causes, typically investigation and transparency failures (see §8.2).

10. Diplomacy: U.S. leadership and the missing coordination mechanism

The United States should lead on:

- standardizing lab designs and robotics designs;
- creating jobs in that build-out;
- passing strong gain-of-function laws as an example the world can follow.

Countries have followed U.S. leadership on research infrastructure before — biosafety levels themselves are the precedent. That only works with early, clear signaling and coordination with allies before others lock into the current conventional-lab path. The window is narrowing as more labs are built.

Honor the President's 2028 commitment to an international conference on lab safety. In the near term, the President should hold conferences domestically and abroad as soon as possible:

raise awareness, reassure the public that the government is paying attention, and signal that future generations will not be left to another COVID — or worse.

The crux is not the technical argument. The technical case is solid. The hard problem is:

How do you get involuntary restrain on a lucrative, security relevant infrastructure decision when the coordination mechanism does not exist?

That may be harder than building the robotic labs. The conferences, the exportable standard, the moratorium, the statute, and ally coordination are that mechanism in draft form. They need to be stood up deliberately, not hoped for.

Technology transfer. High-risk laboratory and pathogen-related technology should not be shared with adversarial communist states. Treat this as an export-control and research-security rule aligned with the moratorium and the DGoF ban — not as a substitute for domestic lab reform.

11. Complementary integrity reforms (conflicts that shape the science)

These items sit beside lab safety because money, fame, and captured evidence streams are part of why dangerous work persisted.

1. Stop allowing pharmaceutical companies to produce and publish efficacy studies of their own products. Shift that function to NIH-funded studies, designed in coordination with FDA and industry.

2. Whistleblower cash awards apply here as well as in the lab — to correct a massive imbalance in who can afford to speak.

3. Major journals. Source notes allege that outlets such as Science were captured into a single permitted position and call for restoring independence and a range of views. In this memo that is recorded as a recommendation to restore pluralism, replication, and independence in high-impact publishing, not as an adjudicated finding of corruption. If the administration wishes to pursue it, it needs a separate evidence annex.

Political diagnosis recorded from source notes, not adopted here as a biosafety standard: that parts of government failed because unelected officials hold lasting power; that greed, vaccine-related money, and fame distort incentives. The operational responses already in this sheet are the revolving-door ban, independent ITPRB classification, NIH-funded (not sponsor-funded) efficacy work, whistleblower pay, and the public database.

12. Immediate action list

This week / this month

• Presidential remarks at home: the blunt GoF line; then incident frequency; then “we will not let this happen again.”

• Direct HHS and NIH to inventory DGoF-adjacent work against the existing funding ban and ITPRB process.

• Announce the construction moratorium on new traditional BSL-3/4 capacity pending robotic standardization.

• Announce NIH whistleblower cash awards (design the program in parallel; do not wait for perfect regulations to say the policy exists).

This year

• Transmit a statutory DGoF prohibition with jail for covert work.

• Draft stricter (initially non-mandatory) lab standards and the standardized interim lab design.

• Stand up the public experiment / dangerousness / debate database.

• Propose the HHS/CDC/NIH revolving-door statute.

• Begin ally consultations on a shared moratorium and robotics standard; restrict high-risk tech transfer.

• Charter the lab-safety division.

By 2028

- Hold the international lab-safety conference the President committed to.
- Have a U.S. robotics-only reference design far enough along that other countries can wait for it rather than pour conventional BSL-4 concrete.

13. Close

This is a remarkable moment: AI and automation can deliver multi-generational solutions, including standardized robotic laboratories. The irony is that the new threat arrives in the same window, before those laboratories exist.

59. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Defining the scope as all organisms capable of causing human disease is overly broad. Some organisms widely used in modern biological research, such as E. coli, may cause human disease under certain conditions but should not automatically be included. The same principle applies to genetically modified cell lines. Many are harmless and widely used in research, despite having been genetically modified, and should not automatically fall within scope. Exemptions should be based on a risk assessment rather than a blanket definition.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Not clear and how is it going to be enforced. What is the repercussion for non-compliance.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: For private pharmaceutical settings, public disclosure can pose significant intellectual property risks that do not appear to have been adequately considered.

6. Other feedback relevant to this resource: This needs to be more detailed and better throught out.

60. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical, engineering, and agricultural research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: '-It is unclear who at a given academic institution should or must be selected as the Authorized Organizational Representative (AOR). Is this person serving as just a point of contact for the institution or would the person in this role have specific authority and responsibilities under the amended Guidelines? Please clarify who at an institution is expected or recommended to serve in this capacity. Would there be personal/professional consequences or implications for the person service as AOR in the event of an institutional lapse or failure to meet the guidelines?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: '-ABSOULTELY REMOVE the encouragement for an individual PI to report directly to the federal level for potential incidents. THIS WILL ABSOLUTELY CIRCUMVENT INSTITUTIONAL AUTHORITY AND SPECIFIC INSTITUTIONAL REPORTING PROCEDURES PUT FORWARD BY THE GUIDELINES. THIS RECOMMENDATION WILL PUT HUMAN AND ANIMAL LIVES AT RISK DUE TO UNDERREPORTING OR DELAYS IN INSTITUTIONAL AWARENESS ABOUT POTENTIAL INCIDENTS. In fact, IBCs would be completely unaware about potential incidents and this could result in significant delays in an institution's ability to respond appropriately in the interest to personnel and public safety!!!! Instead, recommend that PIs self report all potential incidents directly to the Institutional Biosafety Committee. This would help promote reporting and compliance by both the researchers and the institutions.

-Please keep the 3 year renewal plan rather than a de novo form after 3 years for previously approved protocols. Forcing PIs to submit de novo protocols for ongoing research that is well established and appropriate has the potential for significant confusion, protocol numbering/reporting errors (for ongoing work under multiple de novo protocol numbers over time). This would also create unnecessary paperwork and review work for both PIs and the Institutional Review panel members.

-Please specify/clarify institutional reporting of influenza in research personnel. Would this include institutional research personnel contracting influenza in a public sphere at the institution (i.e. interactions with people or animals at the institution outside the capacity of an influenza research focus)

or only those researchers specifically working with influenza as the focus of their research?

-What quantity is considered a "minor spill" of low risk agents? Depending on the type of research being conducted, one researchers "minor spill" could be a mL, for another a Liter!

-Add specific information regarding the level of registration/certification (Ex. "such as ABSA, etc.", training, and experience required to be a Biosafety Official or someone overseeing/supervising Biosafety Level 3 or 4 facilities in which NIH work is conducted. At present, anyone even those without biosafety background or experience would be able to run a secure facility, which leaves a wide door open for poor oversight, poor biosecurity, or poor responses following potential break in containment at such a facility.

-What risk group would/should new "biologics" requiring clinical trials and translational research fall under?

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Draft Meeting Minutes- It would actually be helpful to have the "New IBC Registrations and Amendments for Review (repeat for each registration)" as a separate addable page that each research group PI would be required to complete when submitting their protocol to the institutional review committee for approval rather than making the IBC Chair or equivalent collecting this information from multiple separate forms or PI attachments/emails before, during, or after the IBC meeting. This would streamline and standardize the protocol submission, approval, and reporting process for new IBC registrations and amendments across institutions. Make the individual PIs "generate the New IBC Registrations and Amendments for Review (repeat for each registration) " rather than the IBC Chair or institutional organizational leaders.

Conversely, this could be streamlined to just include written summaries of the proposed work rather than so many small detail boxes which are the bare minimum of what we go over as a committee prior to approving any protocol. Why would the federal government need that level of detail over ever approved protocol nationwide if the institutional oversight at that level is sufficient?! Our protocol forms are even more detailed than the reporting items requested but we are not allowed to attach those forms, but a summary of proposed research is considered not detailed enough by the fields on your proposed template form. Either make every research PI fill out their own detailed form using the same template for uniformity or allow IBCs to provide the simple paragraph summaries for those protocols for which they have reviewed and approved their own highly detailed protocol forms. Right now, this seems to redouble the effort required by making IBC fill out a detailed form using their own more detailed form without condensing any information whatsoever. We need LESS work to do on IBC not more.

6. Other feedback relevant to this resource: Primary clarification- Who would be the appropriate person at an institutional level to serve in the Authorized Organizational Representative (AOR) role and what would their specific responsibilities and authority be over research and reporting at that institution, or is this primarily a "point of contact role"?

61. Zdenek Svindrych

I am responding: On behalf of myself

Name: Zdenek Svindrych

Name of Organization: Dartmouth College

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Dartmouth College

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Human primary cells or established cell lines, without genetic modifications, are not in the scope of the proposed policy. Under current guidelines these are BSL-2.

Does the "other than plants" also imply "other than plan cells"? In that case plant cells expressing prions or toxins would not be covered by the proposed policy, though the toxins themselves wouls.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): no comment

3. Continued utility of Risk Groups: no comment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): no comment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: no comment

6. Other feedback relevant to this resource: no comment

62. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

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After reviewing the policy several times, I am unable to understand how it can be considered logically coherent or feasibly implemented by the regulated community in its current form.

The statement that the intent of the new policy is to “expand the scope of the NIH Guidelines to all biohazards while removing red tape for low-risk research” is difficult to reconcile with the apparent expansion of oversight to include activities that were previously exempt. The policy states that its scope encompasses research involving biohazards, defined as “research involving known or potential risks to human health.” However, it subsequently discusses oversight of BSL-1 and ABSL-1 research, which, by definition, does not pose a risk to healthy humans. This is particularly challenging because the policy appears to eliminate exemptions for all BSL-1 and ABSL-1 containment work.

Requiring activities that were previously exempt to undergo, at minimum, delegated review—and requiring institutions to report to NIH if this zero-risk work proceeds before approval—provides no apparent benefit to human health or safety. Instead, it imposes a substantial administrative burden on covered entities and researchers and adds precisely the type of red tape the policy claims to remove. If NIH does not intend to cover activities that were previously exempt, that should be stated clearly. If the policy’s true objective is to protect human health and safety while minimizing unnecessary administrative requirements, then all work conducted at BSL-1 or ABSL-1 containment should be exempt from IBC reporting and review.

Similarly, the overly broad definition of “toxin,” as well as the addition of chemically or radiologically induced mutations as covered activities, appears unlikely to provide a meaningful benefit to human health while creating additional administrative burdens. Why not establish quantitative criteria for defining toxins, such as an LD50 threshold? Clear criteria would allow institutions to provide enhanced oversight for work that may pose a meaningful risk to human health while preventing the misuse of resources on materials of negligible concern. As the policy recognizes for proteins, toxins are more appropriately considered chemicals and should therefore be regulated through existing chemical-safety requirements. Likewise, coverage of chemical and radiological methods used to induce mutations appears redundant with existing regulatory oversight and is therefore unnecessary. The resulting biosafety considerations are also very low risk and should not warrant additional oversight, much like the breeding of transgenic mice.

At our institution, I estimate that adding protocol reviews for currently exempt activities alone would increase the number of required protocol reviews approximately sixfold. Implementing this change within six months would not be feasible without adding staff. In addition, because protocols would require review every three years, institutions could face recurring surges in workload as large groups of protocols become due for renewal simultaneously. If NIH truly intends to impose this additional burden on covered entities, I ask that the six-month implementation period be reconsidered and extended—particularly for activities that present little or no risk.

I am also concerned that the requirement to publicly post incident reports and submit them to NIH could create health and safety risks by discouraging researchers from reporting incidents to their institutions, particularly when the activities involve no or minimal risk. This approach could transform biosafety professionals into enforcement personnel rather than allowing them to cultivate the trusting, collaborative relationships with researchers that are essential to identifying and addressing problems before they result in exposures or releases. The potentially punitive nature of the requirement is reinforced by the request to include grant information on the reporting template. Is this information truly necessary, especially when institutions may be expected to report relatively minor events?

In short, it would be welcome if NIH were genuinely interested in reducing administrative burdens associated with low-risk research. In its current form, however, this policy appears to exacerbate those burdens. I urge NIH to reconsider the scope of the policy so that institutions can direct their resources toward activities that present meaningful risks and require enhanced oversight.

This is not gold-standard biosafety supporting gold-standard science; it is unnecessary bureaucracy and inefficiency.

63. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: six month implementation timeline is unrealistic. The policy becomes effective six months after publication of the final version and appears to require approved Biosafety Assurance before research may continue. Even at institutions with robust biological safety and security programs, most will need to update or create redaction procedures; modify protocol management systems (whether they be in house or purchased from a vendor); develop new training materials - more so figure out what the PIs will be presenting since it is now their responsibility as outlined in this draft; expand protocol inventories; train investigators, IBC members, and biosafety staff; establish new incident reporting policies

64. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Government Agency

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. "Clinical research cannot be initiated until IBC, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained."

This should be clarified, such as "clinical research, as pertains to the scope of this policy,..."

As written, this could be interpreted as ALL clinical research requires IBC approval, even a research project that is just a retrospective chart review.

2. "Research with primary cells that may be contaminated by adventitious agents"

As written, this could be interpreted as ALL clinical samples that contain cells (such as a blood draw) require IBC approval, as even donor screening cannot rule out all adventitious agents and the guidance as written states "MAY be contaminated". I think this language needs refinement and could cause unforeseen regulatory problems/considerations for institutions to have it written this broadly in scope.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: I think it is at least a good starting point to have Risk Groups. It makes sense to me to have a good baseline be RG level = BSL and then you upgrade or downgrade based on risk assessment, but it gives institutions a starting point.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Helpful, but some of the guidelines overlap with other institutions, such as the SRSS at the VA is already reviewing "Research with primary cells that may be contaminated by adventitious agents".

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It would be better, in my opinion, to have a draft meeting minutes template that is required to use OR an institution may use

their own template as long as their template contains, at minimum, the same details and information required in the template.

6. Other feedback relevant to this resource: N/A

65. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Modernization should not be an unfunded mandate.
This draft substantially expands biosafety oversight responsibilities, increasing transparency, establishing new reporting obligations and requires expanded institutional infrastructure. The policy does not identify corresponding funding mechanisms to support these mandated activities. Depending on the institute, this proposal may required new and or additional biosafety personnel, expanded administrative support, new and or improved information technology infrastructure, public reporting systems, training development, increased protocol management capacity, enhanced institutional oversight activities. This could bring about substantial new and or additional costs to smaller institutions, teaching focused universities, hospitals and emerging and re-emerging research organizations

66. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: the proposed changes may require substantial new staffing and infrastructure investments. The proposed draft does not appear to be complete with the following "Thus, NIH intends to provide additional supplemental materials for the community through implementation resources." stated within but i do not see solid training resources listed, guidance documents for what is required to support this tranisition

67. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: there is a huge security issue with publicly reporting PI names, grant numbers, and other information that is "publicly available". This will bring about reporting culture and public interpretation of incidents issues.
PI's are presently targeted and have been targeted in the past for the type of research they conduct. PIs children have been photographed as they enter their elementary schools and PIs homes have been fire bombed.
This is a prime example of individuals not reporting.

6. Other feedback relevant to this resource: N/A

68. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: the public reporting may undermine the voluntary near miss program.
The federal system is designed around confidentiality and de-identification, while the institutional system requires public reports. The boundary between a mandatory lower risk incident and a voluntary near miss, secondary, failure, or procedural issue is not defined.

6. Other feedback relevant to this resource: N/A

69. Shawn Lupold

I am responding: On behalf of myself

Name: Shawn Lupold

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support efforts to modernize biosafety oversight, but I oppose this draft policy as written. The proposed NIH Biosafety Policy for Research Involving Biohazards is too broad and too ambitious, and it is much more likely to overburden the research system and slow the pace and productivity of NIH-funded science than to meaningfully reduce harm.

My biggest concern is the extremely broad definition of "genetic modification," which appears to capture a wide range of common methods and fields that are essential for the mechanistic rigor expected in NIH-funded research. If implemented as written, this policy would sweep too much routine and low-risk work into formal oversight, overwhelm IBCs and institutional systems, greatly increase administrative costs, and significantly delay the initiation of new studies.

I am also concerned that the extensive public posting requirements for minutes, incident reports, and other materials would place further strain on already underfunded and administratively overloaded research institutions. At a time when investigators and institutions are already burdened by extensive compliance and documentation requirements, this proposal would add substantial paperwork and delays without clear evidence of proportional benefit.

NIH should significantly narrow the scope of this policy, better define truly high-risk activities, and avoid creating an oversight framework that impedes research more than it improves safety.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support the general principle of tiered oversight and agree that some federal oversight is appropriate, especially for NIH-funded research and for higher-risk or novel work. However, the draft policy as written appears insufficiently calibrated to risk and is likely to pull too much routine, low-risk research into expanded oversight. This risks overwhelming both federal and institutional review systems, slowing the initiation of studies, and diverting attention away from research that truly warrants heightened scrutiny. Federal oversight should remain focused on clearly high-risk, novel, or uncertain activities, while local oversight should be streamlined for routine and well-understood work.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting and meeting minute requirements appear likely to create substantial additional administrative burden for investigators, IBCs, and institutions. In particular, the public posting expectations for minutes, incident reports, and related materials may be difficult to manage in practice and could further strain already under-resourced research and compliance systems. These requirements risk increasing paperwork and delay without clear evidence of proportional safety benefit. NIH should simplify these templates and limit required public posting to only what is truly necessary for transparency and accountability.

6. Other feedback relevant to this resource: N/A

70. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: there are ambiguities in the following:
1. any incident at high containment is broader than the examples provided
2. basic first aid and agent specific treatment are not defined
3. a minor spill may be excluded while another provision captures any BSL1 or BSL2 incident.
4. an animal bite or scratch must be reported to the IBC even without biohazard exposure - provided it occurred during research subject to this policy

A compliance violation may be reported to the NIH even if it presents no actual safety risk?

6. Other feedback relevant to this resource: N/A

71. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Healthcare Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: '-Are recombinant plants going to be regulated by the USDA or another group? I have strong concerns about potential recombinant plants spreading into wild type, which could be detrimental to our farms and food supply.
-It would be very helpful to include the BSO section that this individual should be a Subject Matter Expert in this area.
-It would be very helpful to define "adventitious agents."
-Will all human samples have to be regulated by IBCs? Human samples are RG2/BSL2 automatically, including work with non-fixed human tissues. Could this be an exemption?
-Will there be any exemptions for transgenic animal research? There are many animal strains that are considered exempt now and pose very little risk. The administrative burden of the IBC reviewing all these studies would be very large.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: '-Are aggregate publicly available incident reports for non-NIH reportable incidents acceptable? This would help prevent HIPAA concerns and provide a better explanation of what occurred at the institution.
-It feels like these guidelines are leaning very heavily on the BMBL. My understanding was that the BMBL was guidelines, not rules, so this is a difficult concept to change my mind about. I also feel like there are gaps in the BMBL that were previously addressed in the NIH guidelines, but will no longer be addressed.
-Will all teaching labs be required to have IBC approval, even if they are only doing basic BSL1 recombinant work in their teaching labs? The administrative burden of maintaining IBC approval for this

type of work is very large, although the risks are incredibly small.
-BSL1 biological agents in clinical settings should also be under IBC oversight, especially with the use of needles and aerosols. The risk is greater for these procedures and they clinician is at greater risk.
-It is unclear to me if the delegated/sub-group review can only occur after full committee review as amendments or in general. It is worded in a confusing way.
-Respiratory protection is not a universal clinical precaution. It would be better to say, ..."universal precautions, such as glove and mucus membrane protection."

72. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: training is required but no minimum standard or responsible authority is established
the proposed policy does not clearly allocate responsibility for delivery, documenting, and verifying required training.
the institution must ensure training for BSO, IBC members PIs and laboratory staff while the PIs must provide or coordinate trainng for personnel. The policy also requires posting synapses of relevant staff training but does not define content, frequency, competency assessment, NIH provided training or documentation standards.

73. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: assurance approval is a prerequisite, but the policy provides no transition mechanism.
No covered research may be conducted until NIH approves the institutions written biosafety assurance.
The policy applies to all existing awards and ongoing intramural studies six months after publication of the final policy. Assurance may be approved for up to four years.
if the NIH has not approved eveery recipients assurance by the effective date, those who have not been approved appear to have to stop all research until the date approved.
The revision does not allow for provisional assurances, deemed approvals , phased implementation, or continued operation while an assurance is under review.

74. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: No covered research may be conducted until NIH approves the institutions written biosafety assurance
DOES THE NIH HAVE THE PEOPLE POWER TO GET THIS DONE IN A TIMELY FASHION SO THERE IS NO DISRUPTION IN RESEARCH.
such a disruption could have an effect on current and future funding since PIs might not be able to meet their current grant obligations of timely reporting if their research is halted because the NIH does not have enough qualified people to review and approve an institutions biosafety assurance.

75. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: BSO responsibility is defined but BSO authority is not.
the BSO is responsible for inspections, reporting significant problems (what is significant???) incident investigation - documentation?!? distribution to who?!?, and technical advice
the polciy does not provide corresponding authority to access facilities and records, stop unsafe work practives, require corrective actions, or elevate unresolved concerns directly to institutional leadeership.
the policy creastes an accountability mismatch - the BSO may be held responsible for functions that the policy does not empower the BSO tpo carry out

76. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: "Genetic modification" is expansive enough to capture conventional selection and non-biological hazard programs
The definition includes stable alterations produced through passaging, reassortment, chemical means, or radiological means.
This creates several internal tensions:
• The policy is framed as biosafety oversight of biohazards, but the definition may capture organisms altered through chemical mutagenesis or irradiation.
• Genetically modified RG1 agents require delegated review, even if the modification does not plausibly increase risk.
• An organism selected through passage could be regulated as genetically modified even without recombinant or synthetic nucleic acid manipulation.
• The definition may turn attenuation by passage into "genetic modification," while the wild-type definition excludes organisms with deliberately introduced modifications.

This will take significant resources to identify some of the lower-risk research involving this new definition (e.g., passaging RG1 organisms), as well as harmonizing with chemical and radiation oversight - another significant burden without a benefit of mitigating risk. These types of modifications will be easily

identified and reviewed at RG2 and higher, as "WT" organisms with that level of risk are also covered under the policy draft.

77. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: the proposed National Biosafety Data and Safety Analysis Center provisions in the draft policy is unclear - whether the goal is to streamline existing reporting pathways or create an additional reporting requirement given the potential duplication with FSAP, CDC, USDA, OSHA, and other federal partners. Improving transparency and learning from biosafety incidents, especially LAIs, is central to the biosafety profession.

78. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: NIH determinations are described as both project-specific and generally published precedents
IBC petitions must contain experiment-specific details, including modifications, biological systems, manipulations, reagents, animal work, local containment, and the institution's risk assessment. NIH then publishes approved determinations for lower-containment research.
Unresolved issue: It is unclear whether a published NIH determination:
• applies nationally to equivalent work;
• is limited to the requesting institution;
• is limited to the named PI, facility, construct, or procedure; or
• may be relied upon by a different IBC without another NIH petition.
This directly affects whether the approval system becomes a reusable national resource or a series of duplicative case-by-case requests.

79. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: “Well-characterized cell lines” are assigned delegated review without a clear scope basis
The scope applies to cells or organisms containing covered agents or modifications, but Section IV-3 separately lists research with well-characterized cell lines.
Unclear result: A non-recombinant, well-characterized human cell line may be included under IV-3 even when it is not known to contain a pathogen and does not independently satisfy the scope definition.
Conversely, Section IV-2 requires full IBC review of primary cells that “may” contain adventitious agents.
The policy needs explicit criteria distinguishing exempt cell culture, delegated review, and full review.
why duplicate what the OSHA Bloodborne Pathogens Standard currently covers

80. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Draft Does Not Clearly Demonstrate a Reduction in Administrative Burden for Low-Risk Research
One of the primary objectives stated throughout the modernization effort was to expand oversight of higher-risk activities while simultaneously reducing unnecessary burden for low-risk research. The draft successfully broadens oversight to include many biological hazards beyond recombinant and synthetic nucleic acid technologies; however, it is less clear how the proposal reduces burden for lower-risk activities.
Several provisions may actually increase review and documentation requirements for activities historically considered low risk, including:
• Certain RG1 genetically modified organisms (e.g., commercially available ABSL-1 mice/rats);
• Transgenic organisms maintained at ABSL-1 or BSL-1;
• Certain plasmids and viral vectors;
• Well-characterized cell lines;
• Lower-risk incident reporting; and
• Expanded delegated-review documentation requirements.
Additionally, the proposal creates new documentation, transparency, reporting, and public-record obligations that may increase administrative workload at all levels of oversight. NIH should more clearly demonstrate how the proposed framework achieves its stated goal of reducing administrative burden for

low-risk activities and should consider additional exemptions, registrations, or administrative-review pathways where biosafety risk is well understood and minimal.

81. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Facility responsibility is assigned to the PI even when facilities are institutionally managed
The PI must ensure the “integrity, maintenance, and correct functioning” of facilities, physical containment equipment, and PPE. The institution and BSO also carry programmatic and inspection responsibilities.
Conflict: A PI may control use of equipment and reporting of defects but not building ventilation, certification contracts, capital repairs, emergency power, or institutional maintenance systems. The policy should divide responsibility among the institution, facilities owner, BSO, PI, and equipment user.

82. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: BSOs Remain Underdeveloped Despite Expanded Reliance on Risk Assessment
The draft repeatedly emphasizes risk assessment as the cornerstone of oversight, yet devotes relatively limited attention to the qualifications, authority, and role of BSOs.
The policy assigns BSOs responsibilities such as inspections, incident response, reporting concerns, and technical consultation. However, it does not establish:
• Minimum qualifications;
• Competency requirements;
• Continuing education expectations;
• Certification standards;
• Staffing expectations;
• Reporting independence;
• Stop-work authority;
• Formal authority to require corrective actions; or
• Required participation in protocol approvals or incident determinations.
Further, institutions without a designated BSO may simply assign these responsibilities to another institutional official, raising questions regarding qualifications, consistency, and independence.
If NIH intends risk assessment to become the central principle of biosafety oversight, then BSOs should

be strengthened commensurately through national competency expectations, training programs, and clearly defined authority.

83. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: should the BSO have a specific registration or certification?

84. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: IBCs Were Given More Responsibilities, Not More Authority
One of the stated goals of modernization was to strengthen local biosafety oversight. However, the draft primarily increases IBC responsibilities without substantially expanding IBC authority.
The policy places significant new obligations on IBCs, including expanded protocol review, incident review, public posting of meeting minutes and incident reports, review of lower-risk incidents, maintenance of public records, and coordination of NIH approval requests. At the same time, the policy does not:
• Provide explicit enforcement authority;
• Establish mechanisms for suspending unsafe research;
• Create accreditation or certification standards;
• Provide enhanced institutional protections or independence;
• Develop standardized national training resources; or
• Provide additional funding to support these expanded responsibilities.
As written, IBCs appear to assume substantially greater workload without receiving corresponding increases in authority, resources, or institutional standing.

85. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: “Laboratory research” includes clinical settings, but clinical research is treated as structurally different
The definition says laboratory research includes clinical settings within BSL/ABSL 1–4 containment facilities. Later, the policy acknowledges that clinical settings generally do not conform to laboratory BSLs.
Why inconsistent: Clinical settings are simultaneously included within a BSL-based definition and described as not conforming to BSLs. A separate definition of clinical research involving biohazards would avoid forcing clinical activity into a laboratory-containment framework.

86. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Toxin scope and toxin oversight do not align
Scope covers “toxins” without an express threshold, but the definition limits toxin to a protein or peptide produced by living organisms that harms humans. Section IV-2 assigns full IBC review to Select Agent toxins, while Section IV-3 permits delegated review for non-Select Agent biological toxin proteins.
Unresolved points include:
• Whether all quantities and concentrations are covered.
• Whether inactive toxin derivatives are covered.
• Whether isolated subunits are “toxins.”
• Whether nucleic acids encoding toxins are treated as toxin research, genetic modification, or both.
• Whether low-toxicity proteins technically capable of harm require delegated IBC review.
• Why peptides are included in the definition but IV-3 refers only to “toxin proteins.”
This is a major administrative-burden issue because the literal language has no de minimis or potency threshold.

87. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Animal hazards are treated inconsistently
The scope covers wild-type agents only when they cause disease in humans, which appears to exclude animal-only pathogens. Nevertheless:
• “Prions and self-aggregating proteins” include materials causing disease in humans or animals.
• “Zoonotic” agents are expressly defined.
• IBC membership must include animal-containment expertise under certain circumstances.
• The policy requires reporting incidents involving covered research animals.
• Risk assessment and containment provisions address animal populations and ABSL containment.
Result: The policy regulates animal-related procedures and environmental consequences, but its threshold definition may exclude the underlying animal pathogen unless it is zoonotic or genetically modified.

88. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Plant exclusion is incomplete and internally awkward Genetically modified plants are expressly excluded, and laboratory research does not mention greenhouses. The policy nevertheless references environmental containment, ecological risk assessment, GDMOs, release risks, and federal Select Agent requirements protecting animal or plant health.

89. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: genetically modified plants are expressly excluded. At a minimum, plants should be considered where a modification creates a plausible food/feed safety, agricultural, or environmental consequence.

This also feels like another example of the “dis-coordinated framework.” USDA, FDA, and EPA each regulate different aspects of biotechnology, while NIH sits somewhat outside that framework despite setting institutional expectations for federally funded research. Those agency authorities do not necessarily replace institutional oversight during the research phase.

If NIH intends to exclude plant research because other federal agencies provide sufficient oversight, that relationship and the handoff points should be explicit. Otherwise, the policy risks creating exactly the kind of regulatory gap the Coordinated Framework is supposed to prevent.

90. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/28/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: “Biological agent” is defined too narrowly for how the term is used
The policy defines a biological agent as bacteria, viruses, fungi, or parasites that cause human disease. That excludes nonpathogenic organisms, animal-only pathogens, plant pathogens, and agents with uncertain pathogenicity. Yet later provisions repeatedly use “biological agent” when discussing RG1 materials, zoonotic agents, genetically modified agents, environmental impacts, and organisms not currently known to cause human disease.

91. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: within the proposed changes, it specifically states the PI is responsible for those working in the lab to understand the requirements of the policy and have received adequate biosafety training for the research they will be conducting.
1. what is the definition of adequate biosafety training
2. at the moment the policy is not complete and there are many holes that have not been filled - there are many references referenced within the proposed policy that have not been created
3. at the moment, biosafety training is the responsibility of the institution and the PI is responsible for the specific training for the research being conducted.

92. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: you use Risk groups throughout but you never define Risk groups

93. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: ALL

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: clarify what you mean by "Inventory"
with biologicals, an inventory changes daily as cells grow and multiply.

94. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: you do not define or give examples of "emerging and zoonotic agents"

95. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: How will you handle clinical trials with this proposed document?
there are completely different risk banding for clinical trials that don't fall into the various biosafety level schemes.

96. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Who is covering Large Scale research? Whose guidance are users going to follow?
Who is going to cover plant research? Whose guidance are users going to follow?

97. Holda Ramos da Silva

I am responding: On behalf of myself

Name: Holda Ramos da Silva

Name of Organization: University of Maryland, Baltimore

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 9/29/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I do not think it makes sense that RG1 pathogens are not subject to the policy, while research involving transgenic organisms maintained at BSL-1/ABSL-1 would require oversight. I can understand requiring IBC review for the creation of transgenic animals; however, what happens when a PI simply purchases a transgenic animal and uses it solely for behavioral studies? Would an IBC protocol be required in that situation, and if so, for what purpose?

In these cases, there is little or no biosafety risk to human health, and any environmental concerns are already addressed through IACUC oversight and institutional animal care and housing programs. Requiring IBC oversight for such activities adds administrative burden without providing a corresponding benefit to safety.

In addition, if this research falls under IBC oversight, would each transgenic animal strain need to be reviewed and documented in the IBC minutes? The policy is unclear on how broadly these requirements would apply and what level of review would be expected.

I believe these issues should be clarified before the final policy is released. Clear guidance is needed regarding when IBC review is required for research involving transgenic animals, particularly when the animals are commercially obtained, maintained under ABSL-1 conditions, and used exclusively for studies that do not introduce new biosafety risks.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Including personnel records, training records, laboratory inspections, risk assessments, and occupational health

requirements in the minutes will greatly increase the time required to prepare them. I made a rough estimate of what would be required from our department, and this would increase the time spent preparing minutes by approximately 70%. It would require nearly a full-time position dedicated solely to producing the required minutes template.

While transparency is important, all of this information is already maintained by the IBC Office and can be provided at any time through a FOIA request. Requiring risk assessments and detailed discussions to be included in the minutes is also unnecessary, as this information is already documented in much greater detail within the IBC protocol itself. Using this template, I estimate that the minutes for each meeting could easily reach 70 pages in length.

The incident reporting templates appear reasonable to me. However, NIH should carefully consider the consequences of making this information publicly available. It would be very easy to identify an individual who experienced a workplace injury based on the information required in the First Report of Injury form. Depending on the pathogen involved, this could narrow the possibilities to only a few laboratories. This may cause embarrassment for individuals who were injured at work and result in unnecessary exposure of their personal information. I would not be surprised if this also increased the potential for future legal challenges or lawsuits.

6. Other feedback relevant to this resource: Instead of requiring Research with primary cells that may be contaminated by adventitious agents to undergo full committee review, this should be eligible for Designated Member Review (DMR). The risk assessment, bloodborne pathogen (BBP) training requirements, and PPE requirements for this type of research are already well established. Requiring full committee review would not provide a meaningful increase in safety and could delay research by up to six weeks while investigators wait for the next IBC meeting before beginning their work.

I also do not see a reason to eliminate exempt categories such as transgenic rodents housed under ABSL-1 conditions. Does this mean that all research involving transgenic mice housed at the institution would require IBC review, even when the biosafety risks and containment have already been assessed by IACUC? There is no increase in safety asking to a PI make an IBC protocol only for the use of a transgenic mice they didn't even create.

Please also clarify what constitutes a minor amendment under Section IV-3. For example, would the addition of a new genetically modified cell line be considered a minor amendment eligible for Designated Member Review (DMR) if it does not alter the risk assessment of a previously approved IBC protocol? In this scenario, the protocol has already undergone full committee review and received approval. If the proposed cell line does not introduce new hazards, containment requirements, or changes to the existing risk assessment, it is unclear whether the amendment would require full committee review or could be processed through DMR.

Clarification on this point would help institutions apply the requirements consistently and avoid unnecessary administrative burden when proposed changes do not affect the overall biosafety risk profile of an already approved protocol.

98. Chetan Seshadri

I am responding: On behalf of myself

Name: Chetan Seshadri

Name of Organization: University of Washington School of Medicine

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/30/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Diseases and Immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 20260929_NIH_Biohazards_Comment.pdf

Re: Request for Comment — Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

I am a physician-scientist in the Division of Infectious Diseases at the University of Washington and Harborview Medical Center, and the Director of the Seattle Tuberculosis Research Advancement Center (SEATRAC). My laboratory conducts research on the immunology of *Mycobacterium tuberculosis*, a Risk Group 3 pathogen. I submit these comments in my individual capacity as a researcher working daily with the kinds of biohazards that would be most directly affected by this proposed policy.

1. Scope (Section II). I support the expansion of scope from recombinant and synthetic nucleic acid molecules to all biohazards, including wild-type biological agents that cause disease in humans, toxins, prions, and other self-aggregating proteins. The current framework creates an inconsistency in which work with unmodified, naturally dangerous pathogens, including *M. tuberculosis*, sits outside the formal federal biosafety oversight structure, while genetically modified derivatives of lower-risk organisms may require full IBC registration. This misalignment does not reflect actual risk and creates unnecessary administrative burdens. The proposed scope is more logically grounded in hazard-based reasoning and better reflects the breadth of contemporary biomedical research. I support this change.

2. Institutional Submissions to NIH (Section III-A). I support replacing the annual IBC registration requirement with a quadrennial institutional Biosafety Assurance, provided the intention is genuinely to reduce administrative burden on institutions and investigators. The assurance model used by IRBs and IACUCs has worked reasonably well, and aligning IBC oversight with that structure is sensible. I would encourage NIH to ensure that the assurance process is streamlined and that the documentation requirements do not in practice recreate the administrative load of annual registrations through a different mechanism. The framing of the assurance as a four-year commitment is welcome.

3. Incident Reporting (Section III-B). I have significant concerns about two elements of the proposed incident reporting framework.

24-hour reporting requirement. The draft policy would require institutions to notify NIH within 24 hours of becoming aware of incidents posing significant risk to human health, including all incidents at BSL-3/ABSL-3 and BSL-4/ABSL-4 containment. While I understand the intent to improve timeliness and situational awareness, I am concerned that this requirement is not calibrated to actual risk. In a BSL-3 research environment, the events most likely to trigger a reportable incident are often potential exposures for which the immediate medical and occupational health response appropriately takes priority over administrative notification. Diverting time and attention to preparing a report for NIH within 24 hours, often before full information is available, could interfere with the optimal management of the event itself. The existing 30-day window for most incidents has served institutions adequately. I would recommend retaining a 24-hour reporting threshold only for incidents with confirmed community risk or confirmed laboratory-acquired infections, and preserving a longer window for other categories of BSL-3/4 incidents where immediate risk to the public is not established. This is consistent with current practice.

Mandatory public posting of all incident reports. I also have concerns about the proposal to require all incident reports, including lower-risk events addressed entirely at the institutional level, to be posted on a public-facing institutional website. I understand and share the goal of transparency. However, the practical effect of requiring public posting of routine or low-risk incidents is likely to be counterproductive. For events that pose no meaningful risk to the community, the time and effort that investigators, IBCs, and communications staff will spend contextualizing and explaining these reports will substantially exceed the public benefit of avoiding misinterpretation by the public, the press, or local regulators. This burden will fall disproportionately on institutions without dedicated communications infrastructure and may create disincentives for thorough internal reporting and documentation. I recommend that mandatory public posting be limited to incidents that are reportable to NIH, and that lower-risk events addressed locally remain subject only to institutional record-keeping

requirements, consistent with current practice. NIH's proposed annual incident summary report would still provide meaningful public transparency at the aggregate level without the risks associated with real-time disclosure of routine events.

4. Lowering of Containment (Section IV). I support the proposed tiered approach to containment reduction, which would require NIH approval only for initial requests to lower containment for RG3 and RG4 agents, while delegating authority for RG2 lowering decisions to IBCs. For laboratories like mine working routinely with RG3 pathogens, the current requirement to seek NIH approval for all containment modifications creates bottlenecks that are disproportionate to the risk in cases where the IBC has already performed a thorough risk assessment. The proposed approach appropriately concentrates federal review where the risk and scientific uncertainty are highest, while reducing unnecessary friction for well-understood agents.

5. Delegated Review (Section IV-3). I support the introduction of delegated review for specified categories of lower-risk research. The current prohibition on delegated review means that IBC time and attention is not well-matched to the actual risk profile of the protocols under review. By permitting an individual member or a subgroup to approve routine, lower-risk protocols, such as work with well-characterized cell lines, non-Select-Agent toxins, or RG2 wild-type agents, the full committee can devote more substantive attention to the complex, higher-risk protocols that genuinely warrant it.

6. Alignment of IBCs with IRBs and IACUCs. I strongly support the proposal to formally establish IBCs as one of the three foundational pillars of institutional research oversight, alongside IRBs and IACUCs. In practice, biosafety considerations are often downstream of and informed by the IRB and IACUC review process, yet IBCs have historically lacked the institutional standing and resourcing that the other committees receive. Formalizing their role and ensuring consistency in oversight structures across these three bodies will benefit researchers, institutions, and public safety alike.

I appreciate the opportunity to provide comment and commend NIH for its extensive stakeholder engagement during the development of this proposal. I urge NIH to give particular attention to the incident reporting concerns raised above, as these represent the elements of the draft most likely to increase administrative burden without a commensurate improvement in safety outcomes.

Respectfully submitted,



Chetan Seshadri, MD
Professor, Department of Medicine
University of Washington School of Medicine
Director, Seattle Tuberculosis Advancement Center
https://seshadrilab.weebly.com
https://seatrac.uw.edu

99. Cetara Baker

I am responding: On behalf of myself

Name: Cetara Baker

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Safety Professional

Date Submitted: 9/30/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: 1. Exemptions: establish clearly defined exemptions for research that presents low/negligible or well-characterized biosafety risk. Removal of the existing exemption framework could unnecessarily increase IBC registration, review, documentation, and tracking requirements for activities that do not warrant continuing institutional oversight. The final policy should identify categories that are outside the Policy entirely versus activities that are covered but eligible for delegated review.

2. De minimis toxin exemption: establish a risk-based or de minimis exemption for biological toxin research involving quantities, concentrations, formulations, or experimental conditions that present negligible occupational or environmental risk. Requiring IBC review solely because a material meets the definition of a biological toxin may impose administrative requirements disproportionate to the actual risk.

3. Clarify whether toxins appearing on the Select Agent list but maintained below applicable Federal Select Agent Program exclusion quantities automatically require full IBC review, or whether quantity and actual risk may be considered in determining the appropriate review category.

4. Existing federal oversight: establish an exemption or formal recognition mechanism for research

already subject to equivalent biosafety oversight by another federal department or agency. Institutions should not be required to duplicate protocol review, inspections, incident investigations, training, corrective-action tracking, or other oversight when an existing federal program provides equivalent protections.

5. Well-characterized cell lines: why routine, well-characterized materials require an approval? Consider exempting well-characterized cell lines that have no identified biohazard beyond risks already addressed through established institutional practices. If NIH retains delegated review, the final policy should define "well-characterized" and explain the biosafety risk that necessitates prospective IBC approval.

6. Routine RG2 work with established containment: Consider whether every project really needs prospective registration. Consider whether routine work with well-characterized RG2 agents conducted at established BSL-2 containment under standard BMBL practices requires project-specific IBC approval, or whether institutions should be permitted to manage defined categories through approved institutional biosafety procedures and periodic compliance monitoring.

7. Primary human cells: Clearly define when primary human cells are considered potentially contaminated with adventitious agents and therefore require full IBC review. The final policy should clarify whether all primary human cells are presumed to meet this criterion or whether review is triggered by specific source, screening, donor, clinical, or other risk factors.

8. Compliance violations: Establish a clear significance threshold for NIH reporting of compliance violations. The phrase "any compliance violations at any BSL/ABSL" could reasonably be interpreted to require external reporting of minor administrative or technical deviations that present no meaningful increase in biosafety risk. NIH should distinguish significant or substantive violations requiring NIH notification from minor deficiencies that may be documented, corrected, and closed through institutional/IBC oversight.

9. Define minor amendments and identify administrative changes that do not require prospective IBC approval, such as changes that do not affect the agent, procedure, containment, exposure potential, or underlying risk assessment.

10. Clarify whether existing documented inspections performed under another federal biosafety program may satisfy periodic compliance-monitoring requirements when they evaluate equivalent requirements. Institutions should not be required to conduct duplicative inspections solely to satisfy separate administrative frameworks.

11. Three-year de novo review: NIH should permit streamlined continuing review for unchanged research with a demonstrated history of compliance rather than requiring complete de novo registration every three years. Full de novo review should be reserved for research involving substantive changes, increased risk, significant compliance concerns, or other defined triggers.

12. Public disclosure exemption for federal/security-sensitive facilities: NIH should establish a defined exemption or alternative transparency mechanism for federal institutions when public posting would

conflict with CUI, OPSEC, national-security, law-enforcement, proprietary, privacy, or other information-protection requirements. Institutions should not be placed in the position of reconciling conflicting federal obligations without clear NIH guidance.

15. Grandfathering existing research: Provide a transition or grandfathering mechanism for research already reviewed and approved under an established institutional or federal biosafety program when the new Policy becomes effective. Existing research should be permitted to continue through its current approval period unless a substantive risk issue requires earlier review.

16. NIH should consider whether institutions whose research portfolio consists exclusively or predominantly of activities eligible for delegated review should be required to maintain the same IBC infrastructure as institutions conducting research requiring full IBC review. For institutions conducting limited, low-risk BSL-1/BSL-2 research, NIH should consider permitting qualified institutional biosafety personnel or another designated institutional reviewer to conduct and document low-risk reviews without requiring establishment and continuing administration of a full IBC, provided defined criteria and escalation procedures are met. Alternatively, NIH should provide a streamlined IBC model for institutions with exclusively low-risk research portfolios, including reduced administrative, meeting, membership, and reporting requirements while preserving a mechanism for escalation to full IBC review when

17. NIH should permit qualified institutional biosafety personnel to document exemption determinations without requiring submission to the IBC for approval. NIH should provide objective exemption criteria and a standardized exemption-determination tool or checklist.

18. Oversight should be proportional to actual biosafety risk. NIH should reserve full and delegated IBC review for activities for which prospective committee oversight meaningfully improves biosafety, while using exemptions, programmatic approvals, reciprocity, and institutional determinations for well-characterized low-risk activities. This would allow institutional resources to remain focused on research and compliance issues presenting meaningful biosafety risk.

100. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: BSO

Date Submitted: 9/30/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: If DoW funds, directs, and oversees a research project and that project received no NIH support, what specific NIH requirements does NIH believe should apply to that project solely because the institution received NIH funding for an unrelated activity.

101. Martin Carroll

I am responding: On behalf of myself

Name: Martin Carroll

Name of Organization: University of Pennsylvania

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/30/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Blood cancers

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The new policy is a broad administrative over-reach that will impede progress in biomedical research and discovering new cancer therapies. The concept of reviewing every new reagent, synthetic nucleic acid, animal strain, cell line variant, etc. is NOT feasible. Implementation of this policy would create an enormous administrative burden for investigators and inspectors. As there is already inadequate funding for biosafety review officer this policy would simply increase the likelihood of less complete and thoughtful review of reagents I strongly advise AGAINST the proposed policy change.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Oversight should be local as these issues are complex and require real conversations between investigators and regulators to ensure safety and compliance. Federal oversight of local inspections is appropriate but too slow to review biosafety in a timely manner.

3. Continued utility of Risk Groups: Biosafety levels are well established and should be the standard approach.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NA

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: NA

6. Other feedback relevant to this resource: NA

102. Saar Gill

I am responding: On behalf of myself

Name: Saar Gill

Name of Organization: University of Pennsylvania

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 9/30/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer immunotherapy, cellular therapy, translational research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Scope captures a very large volume of low-risk work. Under Section II, any research involving genetically modified cells, viruses, or organisms other than plants is in scope. In practice, essentially every molecular biology, immunology, and cell biology laboratory at an NIH-funded institution now requires registered, approved oversight. Section IV-3 confirms this: delegated review is still required review for plasmids, replication-incompetent non-integrating vectors carrying reporter transgenes, well-characterized cell lines, and genetically modified RG1 agents. A graduate student transfecting a GFP plasmid into HEK293T cells is now performing registered research.
The cost is not the review itself. It is the registration, amendment, renewal, and audit infrastructure that must be built and maintained around tens of thousands of protocols posing negligible risk. NIH should establish a genuine exempt category defined by the characteristics of the construct and host, rather than requiring a submission to confirm exemption. Work with replication-incompetent, non-integrating vectors expressing non-toxic, non-oncogenic transgenes in established cell lines at BSL-1 should be documented locally and require no IBC action.
Section III-B separately caps approvals at three years and requires de novo submission thereafter. For a laboratory with a stable platform, this converts a one-time registration into a perpetual cycle of rewriting unchanged documents, while genuinely new risk is already captured by the existing requirement to review amendments affecting the biosafety assessment. Administrative continuation with attestation of no material change would be sufficient, reserving de novo review for BSL-3/4 work, GDMOs, and substantively modified protocols.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The draft's architecture is sound: tiered review calibrated to risk is the right model. The problem is that the tiers, as drawn, place far too much ordinary laboratory work under mandatory review and attach to it a recurring apparatus of re-registration, public posting, redaction, and reporting, whose cost is borne continuously by every NIH-funded institution.
I would urge NIH to:
1. Define a true exemption for low-risk constructs, not a submission that confirms exemption.
2. Replace de novo renewal with attestation for stable protocols.

3. Limit mandatory public posting to annual institutional summaries.
4. Reserve 24-hour reporting for genuine safety events.
5. Commit to a binding timeline for the federal approvals it is newly requiring.
6. State that IBC review of FDA-regulated INDs is confined to containment and handling.
These changes would preserve the policy's safety gains while keeping faith with the commitment to streamline, not accumulate, administrative processes. Thank you for the opportunity to comment.

3. Continued utility of Risk Groups: Regarding NIH's specific question, Risk Groups remain useful as a property of the agent, distinct from BSL, which is a property of the work; Section V-E states this correctly. The practical gap is that the draft gives no framework for how a genetic modification moves an agent between groups, then routes any containment reduction for RG3/RG4 agents through NIH. Published, searchable precedents from prior NIH determinations would reduce burden more than any other single implementation resource, by letting IBCs act locally on constructs NIH has already evaluated.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reporting conflates administrative lapses with safety events. Section III-B requires 24-hour notification to NIH, with a full report within 30 days, for any compliance violation at any BSL, including failure to obtain or maintain IBC approval. A lapsed registration renewal on a BSL-1 plasmid protocol is thereby placed in the same channel, on the same clock, as a laboratory-acquired infection.
This dilutes the signal NIH is trying to collect and consumes staff time on paperwork errors. Because these reports must also be publicly posted, it creates a strong incentive to under-report rather than to self-identify and correct. The 24-hour channel should be reserved for events involving actual or potential exposure, containment loss, or public health consequence, with administrative non-compliance handled through routine institutional reporting and the annual summary.

6. Other feedback relevant to this resource: Section IV-1 requires NIH approval, in addition to IBC approval, before initiating research involving emerging, novel, or zoonotic agents lacking a BMBL classification, and for initial requests to lower the containment level for RG3/RG4 agents. Section III-D commits NIH only to reviewing these in a timely manner. For translational programs operating against IND timelines, manufacturing slots, and enrollment windows, an open-ended serial federal review is a material risk. If NIH inserts itself into the critical path, it should commit to a defined 30-day response interval and specify a consequence if that interval is not met.
Section IV-2 separately brings under IBC review the administration of products capable of shedding, replicating, or integrating. That describes every lentivirally transduced cell product and every in vivo gene therapy now in clinical development, all of which are already reviewed by FDA under IND, by the IRB, and by institutional scientific review. Section II says research under another agency's purview may proceed once that agency's approvals are obtained, but Section IV-2 then requires IBC approval before initiation, which is at minimum ambiguous and will be read conservatively. NIH should state plainly that for FDA-regulated INDs, IBC review is confined to containment, handling, waste, and shedding precautions, and does not re-adjudicate product risk, construct design, or clinical protocol.

Quorum: Requiring at least two unaffiliated voting members, alongside expanded scope and far greater protocol volume, will make quorum the rate-limiting step at many institutions. Unaffiliated members are

volunteers with finite availability. If the requirement is retained, NIH should permit alternates, remote participation, and counting a single unaffiliated member toward quorum where a second has provided a written review.

103. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The broadened scope will increase administrative burden, not necessarily for the committee itself, but for the staff who support it. While potentially cutting committee meeting times, delegated approvals will be time consuming for the delegate/delegates. Shifting the burden does not decrease the burden.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Section III-A
IBC records retention period should not be tied to the date of a financial report that does not get reported to the IBC. This will rely on systems run by other offices. Please specify which IBC documents will be held to this retention period. Only those shared with the grants office, such as approval letters, or all?

Section III-B
Guidance is needed on what identifies a registration as de novo rather than a renewal of the same work. Will committee review reflected in the minutes be enough?

Section III-B
IBC membership states that the IBC should include individuals with expertise in biological safety and physical containment. The duties of the BSO are listed and must be assigned to another official if there is no BSO. Please provide guidance about the expectations for these individuals' training, certifications and experience.

Section III-C
Strengthen the requirement to report any subsequent changes to include all. The PI may not consider something an alteration of biorisk when it may, in fact, be one. The IBC will not have an opportunity to review it until is discovered at an annual review or inspection.

The responsibility of reporting to the NBDSAC should fall to the IBC not the PI.

Section IV-3
This section must more clearly state that a delegate/delegates can review and approve all the bulleted items as an initial submission and as amendments to full committee approved submissions, if this is what was intended.

104. West Virginia University Institutional Biosafety Committee

I am responding: On behalf of an organization

Name:

Name of Organization: West Virginia University Institutional Biosafety Committee

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We support expanding oversight beyond recombinant DNA research to encompass the broader range of biohazards encountered in modern biomedical research. The proposed scope aligns well with the oversight currently performed by our IBC and better reflects today's research landscape. However, NIH should provide additional clarification regarding key definitions, particularly those related to Gene Drive Modified Organisms (GDMOs), to ensure consistent interpretation and implementation across institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed risk-based oversight structure is appropriate, but NIH should carefully evaluate the administrative burden associated with the expanded transparency, reporting, and documentation requirements. For smaller biosafety programs, maintaining public websites, publishing meeting minutes and incident reports, and managing Biosafety Assurance requirements may require substantial additional resources. For our institution, these responsibilities would largely fall to a biosafety office consisting of only two full-time professionals who are also responsible for protocol review, laboratory inspections, training, incident response, risk assessments, and researcher support. NIH should provide standardized templates and tools to support implementation and clarify the responsibilities of the Authorized Organizational Representative (AOR). Oversight requirements should remain proportional to risk and should not detract from core biosafety functions such as laboratory support, risk assessment, and training.

3. Continued utility of Risk Groups: Risk Groups should remain an important component of the risk assessment process, but Biosafety Levels should continue to serve as the primary framework for determining containment requirements. BSL assignments more accurately reflect the engineering controls, work practices, and facility features necessary to mitigate risk. NIH should continue encouraging institutions to consider agent characteristics, genetic modifications, experimental procedures, and exposure potential when determining appropriate containment. Additional guidance regarding expectations for microorganism inventories would also be beneficial.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH can encourage voluntary adoption of the policy through the development of practical implementation resources, model policies, templates, and training materials. Institutions are more likely to adopt recommended practices when expectations are clearly defined and implementation is straightforward. Transparency requirements should be balanced against the risk that scientific or biosafety information may be misinterpreted by individuals lacking relevant technical expertise, potentially resulting in public misunderstanding or unnecessary concern.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed templates provide a useful framework, but NIH should provide additional guidance regarding acceptable redactions and protection of sensitive information, including personnel, grant, and clinical research information. Public disclosure requirements may have unintended consequences if researchers perceive that reporting incidents or near misses could result in public scrutiny, potentially discouraging timely reporting. NIH should also reconsider the proposed 24-hour reporting requirement and allow sufficient time for institutions to perform an initial assessment before submitting a report. Incident reporting should be coordinated through institutional biosafety programs rather than individual investigators to ensure consistency and accuracy.

6. Other feedback relevant to this resource: Additional guidance will be essential for successful implementation. Areas that would benefit from further clarification include definitions and oversight expectations GDMOs, AOR responsibilities, Biosafety Officer qualifications, microorganism inventory expectations, incident reporting procedures, and standards for publicly posted information. Institutions with limited biosafety staffing will require practical implementation tools and sufficient time to develop compliant processes. For a biosafety office staffed by only two professionals, implementation of new website management, public posting requirements, expanded documentation, and additional reporting obligations may require significant operational changes and could divert resources from direct biosafety oversight activities. The proposed six-month implementation period may be insufficient given the scope of the required changes, and NIH should consider a longer transition period.

Overall Comment
The draft policy represents a thoughtful and necessary modernization of biosafety oversight and appropriately expands beyond the historical focus on recombinant DNA research. Successful implementation, however, will depend on clear definitions, practical guidance, realistic implementation timelines, and balancing transparency with administrative feasibility. NIH should ensure that new requirements strengthen biosafety oversight without diverting limited institutional resources away from the primary goal of identifying, assessing, and mitigating biological risk. This consideration is particularly important for institutions whose biosafety programs operate with small staff and limited administrative support.

105. Matt Stinoski

I am responding: On behalf of myself

Name: Matt Stinoski

Name of Organization: West Virginia University

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As a Biosafety Officer, I support expanding oversight beyond recombinant DNA research to encompass the broader range of biological hazards encountered in modern biomedical research. The proposed scope more accurately reflects the work currently performed by institutional biosafety programs and aligns oversight with today's research landscape. However, additional clarification is needed for several key definitions, particularly those related to Gene Drive Modified Organisms (GDMOs), to ensure consistent interpretation and implementation across institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed risk-based oversight framework is appropriate and helps align regulatory requirements with potential risk. However, NIH should carefully consider the administrative burden associated with expanded transparency, reporting, and documentation requirements. For many institutions, particularly those with small biosafety programs, responsibilities such as maintaining public websites, publishing meeting minutes and incident reports, and managing Biosafety Assurance requirements may require significant additional effort and resources.
As a Biosafety Officer, I am concerned that these requirements could place substantial demands on programs that are already responsible for protocol review, laboratory inspections, training, incident response, risk assessments, and day-to-day support of researchers. NIH should provide standardized templates, implementation tools, and clear guidance regarding the responsibilities of the Authorized Organizational Representative (AOR). Oversight requirements should remain proportional to risk and should not divert resources from core biosafety activities that directly support safe research

3. Continued utility of Risk Groups: Risk Groups should continue to play an important role in the risk assessment process, but Biosafety Levels should remain the primary framework for determining containment requirements. Biosafety Levels more directly reflect the engineering controls, laboratory practices, and facility features needed to mitigate risk. Institutions should continue to evaluate agent characteristics, genetic modifications, experimental procedures, and potential routes of exposure when determining appropriate containment. Additional NIH guidance regarding expectations for microorganism inventories would also be helpful, as practices currently vary across institutions.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH can promote voluntary adoption of the policy by developing practical implementation resources, model policies, templates, and training materials. Clear expectations and readily available tools will make implementation more achievable and consistent across institutions. While transparency is important, public disclosure requirements should be balanced against the possibility that highly technical scientific or biosafety information may be misunderstood by individuals without relevant expertise, which could result in unnecessary concern or misinterpretation of institutional activities.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed incident reporting and meeting minutes templates provide a useful starting point. However, additional guidance is needed regarding acceptable redactions and the protection of sensitive information, including personnel information, grant-related data, proprietary research details, and clinical research information. Transparency should not inadvertently compromise confidentiality or institutional interests.
I also encourage NIH to reconsider the proposed 24-hour reporting requirement and allow institutions sufficient time to conduct an initial assessment before submitting a report. Rapid reporting is important, but accuracy and context are equally critical. In addition, incident reporting should be coordinated through institutional biosafety programs rather than individual investigators to ensure consistency, completeness, and appropriate risk evaluation.

6. Other feedback relevant to this resource: Successful implementation will depend on the availability of clear guidance and practical resources. Areas that would benefit from additional clarification include GDMO definitions and oversight expectations, AOR responsibilities, Biosafety Officer qualifications, microorganism inventory expectations, standards for publicly posted information, and incident reporting procedures.
From the perspective of a Biosafety Officer, institutions with limited staffing will need sufficient time and resources to develop compliant processes. Requirements related to website management, public posting, expanded documentation, and additional reporting obligations may necessitate significant operational changes. The proposed six-month implementation period may be insufficient given the scope of these requirements. A longer transition period would allow institutions to implement changes thoughtfully and effectively while maintaining focus on their primary mission of biological risk assessment and mitigation.

Overall Comment
Overall, the draft policy represents a thoughtful and necessary modernization of biosafety oversight and appropriately expands beyond the historical focus on recombinant DNA research. As a Biosafety Officer, I support the intent of the proposed framework and its emphasis on risk-based oversight. The success of the policy, however, will depend on clear definitions, practical implementation guidance, realistic timelines, and a balanced approach to transparency.
NIH should ensure that new requirements strengthen biosafety oversight without creating administrative burdens that could divert limited resources away from essential biosafety functions, including risk assessment, laboratory support, training, inspections, and incident response. This consideration is particularly important for institutions whose biosafety programs operate with small staffs and limited administrative support.

106. Catherine H. Schein

I am responding: On behalf of myself

Name: Catherine H. Schein

Name of Organization: University of Texas Medical Branch

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Allergy and virus epitopes, immune reaction to proteins

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The document did not specificy that the purpose is to control BSL level pathogens. It needs a mention that work with normal expression plasmids (where a single non-pathogenic protein is cloned) and expressed in auxotrophic bacteria (like E.coli K12 strains and yeast cloning strains) do not require approval.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): While the protections in the document for BSL-3 and -4 organisms are approximately what is in use today, it seems as if the document is trying to apply the same level of "approvals" for organisms that pose no threat and research that is today conducted in a BSL1 or 2 lab. This is an unneeded extension of current practice that will add to the time before a project can start and is likely to increase still more indirect costs

3. Continued utility of Risk Groups: Again, why? What is wrong with the current BSL designations, that are copied all over the world.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): BSL precautions are applied in our institution, regardless of where the funding comes from.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reporting seems a bit vague; it has been pointed out that a researcher having a paper cut or other minor injury (say from a glass flask breakage in the autoclave) in the course of work would have to report it as an "incident".

6. Other feedback relevant to this resource: Look, this document is long enough and so vaguely written that one would wonder if any research project can be started. We should not need a higher level of reporting than we currently have.

107. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/1/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Some definitions of biohazards are vague and not in line with the common scientific definitions, which allows for multiple interpretations. The proposed policy is ~ 20 pages long and many terms are overly simplified from the previous (almost 10 times longer) guidelines, which pertained only to nucleic acids. The previously used guidelines had clear definitions and examples of research under different categories, which are lacking from the policy draft.
As an example, under "genetic modification" definition there is a bullet point with "Can be transcribed or translated", which, while uses certain nucleic acid does not generally modify the genome of the cell and, thus, should not be defined as genetic modification. This can create the situation when previously exempt substances (e.g. most of the siRNAs and mRNAs) that were proven as safe over the years fall under the new policy.
Definitions of cells containing covered hazards is also very vague. As an example- should a commercially available cell line with a stable modification for a reporter protein (e.g. luciferase or GFP) fall under the new policy?
The definitions of toxins are also very vague and do not represent thresholds for concentrations, quantities, etc. It would be beneficial to provide a concrete list of toxins with thresholds. Otherwise multiple proteins can be considered "toxins".
Additionally, the definitions of "biomedical research" and "potential risk" are unclear. These can be clarified with examples. In terms of "potential risk"- thresholds should be added to the policy or it should be under institutional oversight (should be specified in the policy).
It is unclear which agency can determine "non-compliance with the policy".
In terms of the oversight, it is unclear who at NIH approves AOR (if this requires approval) and how the Institutional Assurance is submitted and approved, is there a template? what information should be included, etc. What are the criteria for approval/disapproval/withdrawal of approval of assurances?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Vague definitions of "low risk incidents and minor spills".
It is unclear why no BSO is required on the IBC committee for BSL2 work.

While delegated review process is a positive change, guidance and clarifications on the delegated review process should be included.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Transparency requirements and public posting of the incidents are very broad and can impose a significant burden (e.g. reporting within 24h) as well as may potentially cause lack of reporting.
Multiple terms in "reporting" are not defined clearly. As an example "potential release" and "compliance violation" should be defined more specifically.
In many institutions a staff member involved in any incident is directed to the employee health clinic- is this automatically considered a "treatment beyond first aid"?

6. Other feedback relevant to this resource: N/A

108. Henry Levin

I am responding: On behalf of myself

Name: Henry Levin

Name of Organization:

Type of Organization: Government Agency

Role: Investigator/Researcher

Date Submitted: 10/4/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Basic molecular biology and genetics

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: My understand is that the proposed policy requires that each individual DNA plasmid construct would require being included on a registration, with no blanket registrations allowed. My lab literally has made 5000 DNA plasmids. It is a practical impossibility to complete a formal registration of each and every one of these.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

109. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Better define activities requiring review of genetically modified cells and organisms.

110. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: provide objective criteria and exclusions for toxins

111. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: clarify applicability to animal, plant, clinical and translational research.
provide what guidance documents will be used for animal research, plant research, clinical research as well as translational research

112. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Clarify reporting thresholds.
define "any incident"
distinguish between institutional reporting and NIH reporting

demonstrate how this document will protect sensitive and proprietary information - names, institutes, etc.

113. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: draft a policy that avoids unnecessary burden on minimal risk research

114. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: clarify the AOR responsibilities
define institutional authority and accountability
establish expectations for biosafety expertise

115. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Provide guidance documents to assist with the implementation of the final policy

116. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: you have not addressed grandfathering in existing approvals
Please address this major concern

117. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: the implementation time is ridiculous
allow for a reasonable implementation time so the product that you are looking for is achieved

118. Krista Murray, MS, RBP, CBSP

I am responding: On behalf of myself

Name: Krista Murray, MS, RBP, CBSP

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Human medical life science research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: '- During all the listening sessions, the regulated community asked over and over again to deregulate the non-hazardous rDNA research. There is no scientific justification for its oversight by the IBC after all these many years of safe research. Instead, this new policy now regulates it even more; there is no longer an exempt category of research, and even ABSL1 transgenic rodents are no longer exempt. All of these materials should be excluded from the new regulations.

- I find it very curious that agricultural pathogens, and plants in particular, have been excluded from the regulations; environmental impact is just as significant a problem in the realm of global One Health as human health concerns.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: '- On the form, in the question regarding whether the incident has been reported to other agencies, N/A should be an option.

6. Other feedback relevant to this resource: N/A

Uploaded File: Comments-on-Draft-Bio-Policy.docx

Comments on Draft NIH Biosafety Policy for Research Involving Biohazards

I would like to thank the NIH for providing the biosafety community the opportunity to provide comments on the draft NIH Biosafety Policy for Research Involving Biohazards. As a biosafety professional for over 32 years, I take this very seriously in the hopes of developing a scientifically strong regulatory policy that benefits the safety and compliance of the life science programs in an effective and strategic manner. Below please find my comments.

POLICY

- During all the listening sessions, the regulated community asked over and over again to deregulate the non-hazardous rDNA research. There is no scientific justification for its oversight by the IBC after all these many years of safe research. Instead, this new policy now regulates it even more; there is no longer an exempt category of research, and even ABSL1 transgenic rodents are no longer exempt. All of these materials should be excluded from the new regulations.
- I am also disappointed that there is no alignment of the various regulations from the different federal agencies with this new regulation as was discussed in the listening sessions. The OSHA BBP Standard is barely mentioned though it is definitively entwined within the proposed regulations. The Federal Select Agents are hardly mentioned, as are the USDA and CDC permit programs and the new USG Stopping Policy. During the listening sessions the introductory presentations stated the hope to bring these numerous policies from numerous agencies into alignment within one source, to make compliance easier for the regulated community. Based on the draft policy, research institutions must still answer to numerous separate regulations and regulatory bodies.
- I am strongly supportive of the ability to utilize delegated reviewers for low-hazard research now. This will streamline reviews and improve turnaround time for review committees and the PIs.
- I find it very curious that agricultural pathogens, and plants in particular, have been excluded from the regulations; environmental impact is just as significant a problem in the realm of global One Health as human health concerns.
- The question is raised as to why a Biosafety Officer is only required for research at Biosafety Level 3 and 4. It should be required at least at BSL2, as well as for any agency utilizing Federal Select Agents within this policy.
- In regards to the IBC Committee Members, please provide a clearer definition of the member who is “not affiliated with the institution” as this definition has been inconsistent over numerous years under the existing NIH *Guidelines*, and different applicants reaching out to the NIH registering their IBCs have received different interpretations, making it very difficult to identify candidates to meet this requirement. The definition of institutional affiliation still remains murky and inconsistent.
- In regards to the posting of incidents on the website, no requirement for the length of time the incidents must be posted is provided.
- The posting of incidents on the website and at the NIH site, even if anonymized, may risk the confidentiality of the involved individuals, especially when listing the organism involved if they are rare or unusual, or if the work is unique.
- The posting of incidents on the website and at the NIH site, even if anonymized, may place the institution and/or the research group at risk of protests or targeting from activist groups.
- Though the intention of posting incidents is to provide more information on the types of incidents that occur and to determine ways to prevent them in the future, the exact opposite may occur if researchers are afraid to report incidents due to the posting requirement. This may lead to worse outcomes for the potentially exposed individual and less opportunity to prevent future incidents. Researchers will be more likely to hide incidents and fail to report them, leading to potential

complications for their injuries and impeding the goal of corrective actions to prevent future incidents.

- I recommend limitations to the types of incidents that must be reported and/or posted. For example, only incidents with BSL2 agents or higher should be reported, or only if a true health risk or exposure occurs. For example, is it necessary to report a spill of a microtainer tube of an agent within a functioning biosafety cabinet, where the personnel are wearing PPE, and the spill is cleaned up properly right away? Is this really a release? There is no benefit of calling this a spill or release, or of reporting or posting this incident. Reporting a situation like this, where everything worked properly and no one was exposed benefits no one.
- The duties identified as belonging to the Biosafety Officer should be able to be delegated to other members of the biosafety staff. Lab inspections, incident investigations, and technical advice are often provided by other members of the biosafety team working under the Biosafety Officer, and the duties assigned to the BSO in this policy, along with what is typically required of the Biosafety Officer, are too extensive to be performed by just one person, especially at larger institutions that also have other regulatory programs, such as select agents, high containment labs, USDA or CDC programs, BBP programs, etc. The ability to delegate these activities should be stated in the policy.
- Would the Biosafety Officer be expected to serve on each Delegated Review team? Or could a representative from the biosafety team serve on these teams, or would they even be required on the Delegated Review team? The constitution of the delegated review teams is not made clear in the policy; if there are requirements to the constitution it should be specified within the policy. If a biosafety professional must serve on a delegated review team, other members of the biosafety team besides the Biosafety Officer should be able to serve this function.
- The PI should be able to assign a delegate to work under his/her oversight to assist with their responsibilities assigned within the policy; this should be clarified within the policy.
- Toxins need to be better defined- this is too broad. What is the LD50? Not all are proteins or peptides.
- Is the AOR empowered, or is the position just a contact/liaison for the institution? This needs to be defined. If it just serves as a contact/liaison, just call it such- it could be a duty of the IBC Administrator or BSO. If they must be empowered, we must know this to determine what authority the individual must have.
- The requirement to post minutes “for the length of time of the award’s final financial report” is almost impossible for any institution to track and maintain, as this is maintained by a separate office, and multiple protocols with different awards are listed in each set of minutes. Just require a set length of time, like the 5 years otherwise required to be a feasible option for posting and to minimize the recordkeeping burden on the offices.

INCIDENT REPORTING TEMPLATE

- On the form, in the question regarding whether the incident has been reported to other agencies, N/A should be an option.

Sincerely,

Krista Murray, MS, RBP, CBSP

119. Frances Lund

I am responding: On behalf of myself

Name: Frances Lund

Name of Organization: University of Alabama at Birmingham (UAB)

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): infectious disease and immune host defense

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed policy seems appropriate to cover the relevant biohazards.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Agree with the tiered oversight

3. Continued utility of Risk Groups: Risk groups are relevant place to start but seems that the genetic modification (and type of genetic modification) is most relevant to the conversation as to whether RSG should stay same (eg inserting a reporter like EGFP or a peptide sequence that can be followed but doesn't encode a protein), go up (modification that may increase virulence or introduces new proteins etc to the organism) or go down (attenutation, replication deficient etc). The composition of the IBC is most critical as this group makes the initial "call". Seems like there may be value in having online training for new IBC members (and having online training come from NIH so that it's very clear what the policies will be). The community members on the committee need to be there but there also needs to be sufficient training for those individuals to be able to thoughtfully look at risk levels. Not enough knowledge could lead to polar opposite results - things are not approved because they seem dangerous, even though risk is either low or can be appropriately managed or everything gets approved because the members can't identify the potential risks.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: I am most concerned about the required re-approvals. I think that it is fine that our biosafety reviews need to be reapproved every 3-4 years. However, I think that then Biosafety approval should be at the lab level rather than project level. Otherwise, it becomes very difficult to address 'changes". If it is done at the project level, then one project that is under review might have to change protocols etc but the other project that is not under review (yet utilizes the same genetically altered organism) would still be approved because it hasn't been re-reviewed yet. If we

register all our biosafety RGS under one protocol (and amend if we add new organisms)then all projects would have a consistent set of metrics that need to be followed. Mistakes and non-compliance occur most frequently when the rules are not evenly applied.

120. GeneConvene Global Collaborative, Foundation for the National Institutes of Health (FNIH)

I am responding: On behalf of an organization

Name: brinda dass

Name of Organization: GeneConvene Global Collaborative, Foundation for the National Institutes of Health (FNIH)

Type of Organization: Other

Type of Organization - Other: NGO

Role: Other

Role - Other: Technical Expert- Gene Drive Policy

Date Submitted: 10/5/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Genetically Modified Organisms- engineered gene drive organisms particularly mosquitoes, Vector borne diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed policy's focus on the safe conduct of laboratory research is appropriate. NIH should, however, clarify the scope and definition of biohazards to ensure that oversight is proportionate to the risks of the proposed activity and does not unnecessarily impede research on emergent use cases e.g., gene drive mosquitoes or their progression toward potential public-health use.

The presence of a genetic modification or gene drive should not, by itself, constitute a finding that an organism presents an unacceptable risk or requires heightened federal oversight. NIH should distinguish eligibility for biosafety assessment from the outcome of that assessment. Research involving gene drive mosquitoes can appropriately undergo institutional review without presuming that every organism, experimental activity, or research stage presents the same hazards.

The definition of biohazards should require a scientifically plausible basis for concern, informed by the organism's characteristics, the proposed activity, and scientifically credible exposure pathways. References to potential risk should not be interpreted as requiring investigators to eliminate every hypothetical uncertainty. Equally, the absence of a documented adverse effect should not be treated as proof of safety. Information requirements should address uncertainties that could materially change the biosafety decision.

NIH should clarify the treatment of pathogen-free mosquitoes, isolated molecular components, nonviable specimens, and constructs that cannot support gene drive activity under the proposed conditions. These materials and activities should not automatically receive the same oversight as work involving viable organisms capable of transmitting a drive. Clear exclusions, delegated review, and incorporation of existing assessments should be available where justified by the activity's risk. Such determinations should account for whether components could acquire relevant functionality in the

proposed experimental context.
The policy should preserve its explicit exclusion of deliberate/ intentional environmental release. Laboratory biosafety approval should neither authorize deployment nor create a duplicative NIH release-approval process. Field testing and public-health use should remain subject to applicable regulatory and federal, state and local requirements (including those on tribal lands). NIH should clarify how enclosed outdoor and semi-field studies are classified and how relevant determinations by other competent authorities may be recognized.
Any inadvertent oversight gaps should be addressed narrowly. In particular, NIH should reconcile the human-health threshold with consideration of environmentally consequential accidental escape from contained research. This can be achieved through targeted guidance on plausible exposure and adverse-effect pathways, rather than a general expansion of NIH oversight to all environmental effects or all uses of genetically modified organisms. Gene drive mosquitoes should not automatically be treated as novel pathogens merely because they are genetically engineered or lack a listing in a pathogen reference document.

We recommend that NIH expressly state: “Inclusion within the scope of this policy does not establish a presumption of high risk. The level of review, information required, and conditions imposed shall be proportionate to the proposed activity and supported by a documented risk assessment. NIH and institutions shall use the least burdensome oversight sufficient to manage identified scientifically plausible harms to mitigate related risks and shall avoid duplicative review.”

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): GeneConvene supports tiered biosafety oversight where the level of review is proportionate to the risks of the proposed activity. Institutional review should ordinarily be sufficient for contained gene drive mosquito research when an appropriately qualified committee can assess the relevant risks and establish effective safeguards. Federal review should be reserved for clearly defined circumstances requiring additional scrutiny or a nationally consistent determination.

NIH should clarify that genetic modification, gene drive capability, novelty, or uncertainty alone does not establish a need for federal escalation. Escalation should identify the specific concern, its significance for the proposed research, and why institutional review is insufficient. The framework should also provide explicit pathways to reduce administrative burden as evidence accumulates, including delegated review, incorporation of previous assessments, and reliance on materially applicable determinations.

For international research, NIH should clarify funding-related responsibilities, recognize equivalent oversight arrangements where appropriate, and support access to shared scientific expertise. Reviews should be coordinated to avoid duplication while preserving assessment of local facilities and environmental conditions.

Laboratory oversight categories should not become additional authorization requirements for field trials or public-health deployment particularly for international authorities or funders who could treat NIH’s laboratory categories as universal risk classifications or prerequisites for release. That would be an interpretation beyond this policy’s laboratory purpose. Those decisions should remain with the applicable competent authorities so as not to delay laboratory approval of research and prolong the pathway to use. With these clarifications, tiered oversight could support safe research and responsible

progression toward use; without them, ambiguous escalation and overlapping requirements could impose delays disproportionate to the risks.

3. Continued utility of Risk Groups: Risk Groups (RGs) remain useful as an initial reference for assessing infectious agents, including parental agents that undergo genetic modification. Their utility is limited, however, for organisms whose principal biosafety concerns involve escape, establishment, inheritance, or ecological effects. NIH should therefore retain RGs as one input where scientifically applicable, rather than use them as a universal classification system for genetically modified organisms.

RGs, Biosafety Levels, and Arthropod Containment Levels should be clearly distinguished. RGs describe agent hazards; BSLs and ACLs describe combinations of safeguards selected for particular activities. These systems are not interchangeable, and their numerical designations do not establish equivalent risk or containment. Genetic modification should prompt assessment of its functional consequences, without an automatic assumption that it increases risk.
For gene drive mosquito research, NIH should explicitly recognize the Arthropod Containment Guidelines and their gene drive addendum as complementary to BMBL. Assessment should integrate any pathogen-related hazards with mosquito biology, the modification, experimental procedures, and the consequences of unintended escape in the local environment. A containment requirement should not be interpreted as assigning the mosquito to a corresponding pathogen Risk Group.

To support consistent international implementation, NIH should provide worked examples, a terminology guide, and a crosswalk explaining how relevant BSL and ACL safeguards satisfy policy requirements. Such a crosswalk should compare specific measures rather than imply automatic equivalence between levels. Guidance should also distinguish laboratory containment decisions from the environmental risk assessment and authorization required for deliberate field testing or deployment.

This approach would preserve appropriate safeguards while reducing unnecessary escalation, duplicative facility requirements, and inconsistent interpretation across research institutions and national authorities.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary adoption through practical support, accessible expertise, and recognition of equivalent biosafety arrangements which would need to be assessed. The final policy should distinguish informal adoption of its principles from formal voluntary participation and clearly explain the obligations associated with each. Institutions outside mandatory coverage should be able to understand whether participation entails an Assurance, reporting requirements, or other administrative commitments before enrolling.
NIH should preserve and update the voluntary-compliance mechanisms in Section IV-D of the existing NIH Guidelines, including access to institutional biosafety review, requests for relevant determinations, and procedures for handling proprietary information. Implementation resources, training, and scientific consultation should be available to institutions regardless of their funding source.
For international gene drive mosquito research, voluntary participation should accommodate national legal frameworks, institutional structures, and access to shared or regional expertise. NIH should recognize scientifically justified equivalent safeguards and existing assessments, while retaining consideration of local facilities and environmental conditions. Documentation requirements should be

proportionate to the proposed activity and explicit about handling of proprietary information and confidential materials, public disclosure and incident learning information.

Voluntary participation should support institutional capability and confidence in biosafety practice. It should not become an additional authorization requirement for research, collaboration, field testing, or deployment otherwise governed by competent authorities. NIH should also clarify that participation does not constitute product endorsement or environmental-release approval. These measures would encourage broader uptake while avoiding unnecessary duplication and administrative barriers.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: none

6. Other feedback relevant to this resource: none

Uploaded File: NIH_Biosafety_Policy_Formal_Comment-Bdass-oct-2026.docx

Description: attachment has additional text and tables that support the responses provided to the questions above.

Comments on the draft NIH biosafety policy

Gene drive organisms and emerging synthetic biology

To: Office of Science Policy, National Institutes of Health
Re: NOT-OD-26-112
Date: September 30, 2026

Thank you for the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. These comments support rigorous biosafety oversight and recommend changes that would make review scientifically defensible, proportionate, and predictable across gene drive organisms and emerging synthetic biology. The central recommendation is to connect oversight and information requirements to plausible pathways to harm, the proposed research activity, and uncertainties that materially affect the decision.

NIH should preserve robust containment and independent review while avoiding automatic escalation based solely on a technology label, lack of a conventional comparator, or absence from a pathogen reference list. Equally, where a credible potential for severe or widespread harm cannot be adequately bounded, uncertainty should justify additional evidence, federal consultation, or a decision not to proceed. These complementary principles would support responsible innovation without weakening protection of personnel, communities, animals, plants, or ecosystems.

1 Preserve existing safeguards and improve the risk assessment method

The proposal addresses laboratory research rather than deliberate field release. Section V includes likelihood, severity, procedures, genetic modifications, and mitigation. These are appropriate foundations. [1] Existing NIH guidance already establishes Level 2 minimum containment for gene drive modified organisms (GDMOs), NIH approval for reductions, biosafety officer participation, and access to relevant ecological expertise. Those safeguards should not be presented as newly introduced restrictions. [2,3]

Biosafety in Microbiological and Biomedical Laboratories (BMBL) emphasizes protocol-driven assessment, expert review, and periodic reassessment. The World Health Organization (WHO) likewise recommends an evidence- and risk-based approach. [4,5] NIH should make the following sequence explicit: identify protection goals and assessment endpoints; formulate plausible pathways to adverse effects; evaluate relevant evidence and exposure; characterize likelihood, consequences, and uncertainty; select controls; and document residual risk and the basis for its acceptability. The Convention on Biological Diversity (CBD) gene drive guidance offers a useful problem-formulation framework. Its environmental-release focus could be adapted to the laboratory decision at hand, without importing field-release requirements wholesale or implying that the guidance creates any United States legal obligation. [6,7]

NIH should permit qualitative, semiquantitative, or quantitative assessment as justified by the evidence. Numerical probabilities should *not* be required where they would convey false precision. Conversely, general statements that harm is conceivable should not alone justify unlimited data requests. Each request should identify the decision-relevant uncertainty it is intended to resolve. The assessment should distinguish uncertainty due to missing knowledge (epistemic) from biological and natural variability (aleatory) and identify conditions under which the decision would change.

Suggested language: Risk assessments shall be case-specific and proportionate to the proposed activity, organism or biological system, and plausible exposure pathways. They shall identify protection goals,

potential adverse effects, relevant evidence, and uncertainties material to the decision. Information requirements and safeguards shall be justified by their relevance to those pathways. Assessors shall document residual risk, the basis for its acceptability, and conditions requiring reassessment. Initial conservative assumptions shall be revised when reliable evidence supports revision.

2 Tailor gene drive review to biological properties and research stage

Section V-B makes broader GDMO assessment mandatory; the existing Guidelines use a discretionary formulation. [1,2] NIH should clarify that mandatory consideration does not mean an identical, expansive evidence package for every project. The appropriate breadth should follow the drive system, organism, facility, surrounding environment, scale, and research stage.

NIH implementation materials already distinguish spread, persistence, ecological consequences, and biological and environmental containment. [3] Retaining these distinctions would help reviewers avoid treating all gene drives as equivalent. Guidance should encompass vertebrates, invertebrates, fungi and other microorganisms, and clarify the treatment of plant applications. It should distinguish an organism capable of drive activity from an isolated component, a nonfunctional construct, and a conventional genetically modified organism without inheritance bias. Claims of localization or self-limitation should be assessed rather than presumed.

For contained work, a relevant environmental assessment should consider the plausible sequence from escape to survival, reproduction or establishment, spread or persistence, and adverse effects on specified endpoints. Containment should be matched to the species and life stage, including the potential movement of viable material. A biosafety-level label should not substitute for evaluating whether the facility and practices actually prevent the relevant exposure.

Human-pathogen risk groups and containment levels serve different purposes. For gene drive organisms without a primary infectious hazard, NIH should use an additional ecological risk profile rather than force the organism into an infectious-disease classification. Arthropod-specific guidance, including the gene drive containment addendum, should supplement BMBL for insect research. [3,4,8] For vertebrates and other taxa, equivalent species-appropriate expertise should be available.

Suggested language: For gene drive modified organisms, the breadth of assessment shall reflect the specific inheritance mechanism, potential spread and persistence, organism biology, proposed manipulations, and plausible consequences of unintended release. The presence of a gene drive shall not by itself establish a uniform degree of uncertainty or justify the same information requirements for every research stage.

3 Development examples and implications for oversight

Mosquitoes

Malaria mosquitoes provide an advanced contained-research example. Published work includes population suppression in large cages and recent testing of gene-drive-capable mosquitoes against patient-derived malaria parasites in Tanzania. These are distinct milestones; neither should be described as proof of public-health effectiveness following environmental deployment. [9,10] WHO provides a framework for staged testing of genetically modified mosquitoes. [11]

NIH should allow the evidence base from prior studies to inform subsequent assessments where its relevance is justified. An assessment should distinguish pathogen-free insect work from experiments involving infection and should examine the containment implications of the actual mosquito population and location.

Progression to a larger contained study should trigger review of changed exposure opportunities and consequences, rather than automatic repetition of all earlier submissions.

New World screwworm

New World screwworm illustrates why genetic biocontrol must not be equated with gene drive. Genomic research has identified resources relevant to future drive development. More advanced operational innovations include male-only production for sterile insect technique: USDA describes NovoFly as a strain whose released flies undergo irradiation to ensure sterility. These are different biological strategies and evidence bases. [12,13]

NIH should distinguish conventional sterile insects, genetically modified sexing strains, self-limiting systems, and organisms capable of gene drive. The assessment should address the parasitic organism and credible exposure to humans and animals as well as any additional drive-related effects. Prior experience with sterile insect production can inform facility operations where applicable, but should not establish the safety of a fertile drive organism by analogy alone. NIH should provide a clear route for reliance on relevant USDA and EPA findings while retaining review of any remaining laboratory risks not addressed in those findings.

Invasive rodents and other organisms

Mouse research has demonstrated biased inheritance and associated fertility-gene mutations in a laboratory tCRISPR system, alongside modelling of island eradication. The modelled outcome is not evidence that eradication has been demonstrated in the field, and results in house mice should not be generalized to all rodent species. [14]

For invasive-rodent applications, guidance should address the proposed target population, non-target conspecific populations, animal welfare, and the consequences of escape or movement beyond the intended area. The potential conservation benefit of eradication should be described separately from the safety of a particular contained experiment. Other organisms should be assessed using the same principles, with information requirements adapted to their biology rather than copied from the mosquito evidence package.

4 Clarify scope and federal referral thresholds

Section II combines a human-health threshold with exclusions for plants; its interagency reliance provision needs operational detail. Section IV-1 addresses unclassified novel agents. [1] NIH should resolve how these provisions apply to a nonpathogenic gene drive organism, a conservation application, and a synthetic organism without a conventional species classification. Otherwise, both oversight gaps and unnecessary referrals are foreseeable.

A deliberately engineered organism should not require federal review solely because it is novel or absent from BMBL. NIH should define specific referral criteria, including credible potential for serious consequences, inadequately characterized exposure pathways, or uncertainty about whether available controls can adequately reduce risk. These criteria should also capture genuinely consequential synthetic systems that fall outside familiar pathogen categories.

NIH should publish examples distinguishing routine Institutional Biosafety Committee (IBC) review, delegated review, optional scientific consultation, and mandatory federal approval. It should explain the relationship between GDMO-specific requirements and generic low-risk categories. For interagency reliance, NIH should identify which documented determinations can satisfy which requirements, who retains responsibility for

residual laboratory risks, and how conflicting conditions will be resolved. A research grant or an agency relationship alone should not be treated as an applicable biosafety clearance.

If plant gene drives or research with environmental but no identified human-health risk remain outside scope, NIH should identify the rationale, applicable alternative oversight, and route for resolving mixed projects. This comment does not request that laboratory approval confer field-release authorization. NIH should separately clarify the classification of enclosed outdoor facilities and semi-field studies, based on the applicable containment and exposure conditions.

5 Establish an assessment route when no single wild type comparator exists

Sections V-B and V-C rely on parent-organism and sequence-source considerations, including assumptions about function in the original host. [1] These can be useful starting points, but NIH should provide a parallel assessment route for systems for which no single parent is scientifically adequate or available.

Synthetic DNA, synthetic-genome cells, cell-free production systems, and organisms used in biomanufacturing should not be treated as a single hazard class. A synthetic genome may retain substantial biological ancestry: JCVI-syn3.0, for example, was developed through redesign and synthesis of a Mycoplasma-derived genome. [15] Conversely, some prospective systems may combine functions for which no whole-organism comparator adequately describes the hazard. Neither synthetic origin nor a claim of novelty establishes safety or danger by itself.

Where no adequate comparator or history of safe use exists, NIH should accept a weight-of-evidence assessment using relevant chassis information, component functions, functional analogues, system-level properties, and empirical evidence. Comparators may be multiple and endpoint-specific. Assessors should state where analogy is informative and where it fails (transferability uncertainty). A history of safe use should be evaluated against comparable scale, exposure, intended function, and environmental conditions, rather than treated as an unconditional property of a species.

The assessment should address replication, persistence, interaction with other organisms, production of biologically active substances, potential transfer of functional genetic material, detectability, and the effectiveness of proposed controls, as relevant. For biomanufacturing, review should distinguish the production organism, process intermediates, final product, and waste stream. Scale-up, product recovery, and residual viable material can change exposure even when the underlying genetic design is unchanged.

Suggested language: Where no scientifically appropriate parental organism or single comparator exists, assessment shall proceed using a justified combination of functional analogues, component and system-level evidence, and empirical characterization. Lack of a comparator or history of safe use shall be recorded as an evidence limitation whose significance is evaluated for the decision. It shall neither preclude assessment nor establish a presumption of safety. Progression shall depend on sufficient evidence that the proposed activity can be conducted at an acceptable level of residual risk.

NIH should also clarify coverage of acellular nucleic-acid synthesis and synthetic biological products. Scope should turn on reasonably foreseeable biological function and exposure, including relevant downstream use, rather than simply whether a material has yet been introduced into a cell. Sequence provenance, percentage contribution, and computational predictions should inform assessment without substituting for functional context. Initial assumptions should be explicitly revisable.

6 Distinguish mirror biomolecules from self replicating mirror organisms

Mirror proteins and peptides must be distinguished from a self-replicating mirror organism. The 2024 scientific assessment of mirror life identifies serious concerns about possible immune evasion and ecological spread of mirror bacteria, while distinguishing these concerns from research on individual mirror biomolecules. [16]

NIH should assess non-replicating mirror products according to their biological activity, toxicity, persistence, exposure, and disposal requirements. Reversed chirality should not alone trigger the oversight assigned to a self-replicating organism. Conversely, the safety of an isolated mirror protein should not be extrapolated to a mirror cell capable of autonomous propagation.

For research aimed at creating self-replicating mirror organisms, this comment recommends a dedicated federal determination before such creation is authorized. Review should evaluate whether risks can be credibly bounded and whether detection, containment, inactivation, and response assumptions remain valid. Conventional controls should not be accepted solely by analogy to ordinary microorganisms. Where evidence cannot support an acceptable residual risk, the activity should not proceed. NIH should distinguish such work from research that characterizes risks or develops safeguards without enabling organism creation, and should engage relevant federal and international expertise.

7 Anticipate generative optogenetics and programmable biological systems

DARPA's Generative Optogenetics program seeks light-directed synthesis of DNA and RNA within living cells. This is a research objective, not evidence of a mature, unrestricted in-cell synthesis capability. [17] Nevertheless, the prospective ability to change biological outputs through instructions warrants advance clarification of oversight.

NIH should assess both the platform and the range of outputs authorized for a project. IBC submissions should describe the permitted biological functions and the limits of the approved activity sufficiently to determine when changed instructions or generated products require renewed review. Approval of a platform should not be interpreted as approval of every output it might generate. At the same time, minor changes demonstrably within an approved range should not require a complete resubmission.

Future guidance should address traceability of authorized outputs, verification of resulting biological activity, unintended activation or persistence, and changes in scale or exposure. An external control signal should not be assumed to provide complete biological containment. NIH should also coordinate biosafety review with applicable biosecurity and nucleic-acid synthesis screening requirements, recognizing that synthesis within cells may require safeguards beyond those associated with ordering DNA from an external supplier. This is a prospective governance recommendation, not a claim that a particular platform currently bypasses a legal requirement.

Suggested language: For programmable biological platforms, approval shall specify the authorized range of biological functions and the evidence supporting safe conduct. Changes capable of materially altering hazard, exposure, persistence, or control effectiveness shall receive review before implementation. Administrative or technical changes demonstrably within the approved range may be handled through a documented delegated process.

8 Make implementation predictable and proportionate

The proposal introduces approved institutional Assurances and triennial de novo review; it also addresses containment reductions and incident reporting. [1] These processes should strengthen accountability without creating avoidable interruptions in safe research.

NIH should provide transitional recognition of valid existing approvals for a defined period, subject to material safety findings. It should publish completeness criteria and target review timelines, explain when requests for information pause those timelines, and provide an escalation route for unresolved classifications. These procedural commitments should not create approval by default.

For renewals, NIH should permit incorporation of prior assessments and a focused account of changes, incidents, and new evidence. It should clarify whether published containment determinations can support subsequent materially equivalent work and what site-specific confirmation remains necessary. Shared expert resources and *ad hoc* consultants can improve access to ecological, entomological, vertebrate, and synthetic-biology expertise. Scientific independence and conflict management should be preserved without requiring every institution to retain all specialties permanently.

Incident criteria should expressly address environmentally consequential escape, including events without an immediate human infection hazard. Guidance should distinguish a breach within an effective secondary barrier from release beyond containment, while requiring prompt evaluation of both. Public reporting should communicate the event, exposure, consequences, and corrective action accurately, with appropriate protection of confidential information and security-sensitive details. NIH should use aggregated incident learning to improve guidance rather than allow low-consequence events to become misleading proxies for technology-wide risk.

Finally, NIH should maintain updated organism- and technology-specific implementation resources, with examples from mosquito research, screwworm biocontrol, invasive-rodent research, synthetic production systems, mirror biomolecules, and programmable platforms. Periodic consultation with researchers, biosafety professionals, ecological risk assessors, and relevant communities would help those resources evolve with the evidence.

Requested action

NIH is requested to incorporate the proposed methodological language, clarify scope and referral thresholds, and publish practical implementation guidance before the policy takes effect. A coherent framework should enable well-supported contained research to proceed, direct additional scrutiny to uncertainties that matter, and withhold authorization when credible serious risks cannot be adequately controlled. These changes would improve both biosafety and the predictability needed to develop tools for public health, animal health, conservation, and responsible biomanufacturing.

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1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

The proposed policy's focus on the safe conduct of laboratory research is appropriate. NIH should, however, clarify the scope and definition of biohazards to ensure that oversight is **proportionate to the risks of the proposed activity and does not unnecessarily impede research** on emergent use cases *e.g.*, gene drive mosquitoes or their progression toward potential public-health use.

The presence of a genetic modification or gene drive should not, by itself, constitute a finding that an organism presents an unacceptable risk or requires heightened federal oversight. NIH should distinguish eligibility for biosafety assessment from the outcome of that assessment. Research involving gene drive mosquitoes can appropriately undergo institutional review without presuming that every organism, experimental activity, or research stage presents the same hazards.

The definition of biohazards should require a scientifically plausible basis for concern, informed by the organism's characteristics, the proposed activity, and scientifically credible exposure pathways. References to

potential risk should not be interpreted as requiring investigators to eliminate every hypothetical uncertainty. Equally, the absence of a documented adverse effect should not be treated as proof of safety. Information requirements should address uncertainties that could materially change the biosafety decision.

NIH should clarify the treatment of pathogen-free mosquitoes, isolated molecular components, nonviable specimens, and constructs that cannot support gene drive activity under the proposed conditions. These materials and activities should not automatically receive the same oversight as work involving viable organisms capable of transmitting a drive. Clear exclusions, delegated review, and incorporation of existing assessments should be available where justified by the activity's risk. Such determinations should account for whether components could acquire relevant functionality in the proposed experimental context.

The policy should preserve its explicit exclusion of deliberate/ intentional environmental release. Laboratory biosafety approval should neither authorize deployment nor create a duplicative NIH release-approval process. Field testing and public-health use should remain subject to applicable regulatory and federal, state and local requirements (including those on tribal lands). NIH should clarify how enclosed outdoor and semi-field studies are classified and how relevant determinations by other competent authorities may be recognized.

Any inadvertent oversight gaps should be addressed narrowly. In particular, NIH should reconcile the human-health threshold with consideration of environmentally consequential accidental escape from contained research. This can be achieved through targeted guidance on plausible exposure and adverse-effect pathways, rather than a general expansion of NIH oversight to all environmental effects or all uses of genetically modified organisms. Gene drive mosquitoes should not automatically be treated as novel pathogens merely because they are genetically engineered or lack a listing in a pathogen reference document.

We recommend that NIH expressly state: "Inclusion within the scope of this policy does not establish a presumption of high risk. The level of review, information required, and conditions imposed shall be proportionate to the proposed activity and supported by a documented risk assessment. NIH and institutions shall use the least burdensome oversight sufficient to manage identified scientifically plausible harms to mitigate related risks and shall avoid duplicative review."

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).

GeneConvene supports tiered biosafety oversight where the level of review is proportionate to the risks of the proposed activity. Institutional review should ordinarily be sufficient for contained gene drive mosquito research when an appropriately qualified committee can assess the relevant risks and establish effective safeguards. Federal review should be reserved for clearly defined circumstances requiring additional scrutiny or a nationally consistent determination.

NIH should clarify that genetic modification, gene drive capability, novelty, or uncertainty alone does not establish a need for federal escalation. Escalation should identify the specific concern, its significance for the proposed research, and why institutional review is insufficient. The framework should also provide explicit pathways to reduce administrative burden as evidence accumulates, including delegated review, incorporation of previous assessments, and reliance on materially applicable determinations.

For international research, NIH should clarify funding-related responsibilities, recognize equivalent oversight arrangements where appropriate, and support access to shared scientific expertise. Reviews should be

coordinated to avoid duplication while preserving assessment of local facilities and environmental conditions.

Laboratory oversight categories should not become additional authorization requirements for field trials or public-health deployment particularly for international authorities or funders who could treat NIH's laboratory categories as universal risk classifications or prerequisites for release. That would be an interpretation beyond this policy's laboratory purpose. Those decisions should remain with the applicable competent authorities so as not to delay laboratory approval of research and prolong the pathway to use. With these clarifications, tiered oversight could support safe research and responsible progression toward use; without them, ambiguous escalation and overlapping requirements could impose delays disproportionate to the risks.

Issue	Our assessment	Amendment sought
Institutional review as the normal route	Appropriate for contained research where risks can be assessed and managed locally.	Confirm that an adequately supported IBC determination is sufficient unless a defined federal trigger applies.
Federal escalation for novelty or uncertainty	Potentially overbroad if interpreted to capture every new mosquito strain or construct.	Require a documented, decision-relevant concern. Genetic modification, novelty, or absence from a pathogen handbook should not alone trigger escalation.
Reducing oversight as evidence accumulates	Essential for genuine calibration to risk.	Provide routes to streamlined review, reliance on prior determinations, and justified containment reductions.
Repeated and overlapping reviews	Could consume resources without improving the decision.	Permit parallel reviews, reuse of relevant evidence, and clear allocation of responsibilities.
IBC discretion	Valuable, but decentralization alone does not ensure proportionate decisions.	Require reasons for additional conditions and provide access to expert consultation and reconsideration.
International implementation	Potentially burdensome where expertise and administrative resources are limited.	Allow shared expertise and recognition of equivalent institutional arrangements, with site-specific assessment retained.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Risk Groups (RGs) remain useful as an initial reference for assessing infectious agents, including parental agents that undergo genetic modification. Their utility is limited, however, for organisms whose principal biosafety concerns involve escape, establishment, inheritance, or ecological effects. NIH should therefore retain RGs as one input where scientifically applicable, rather than use them as a universal classification system for genetically modified organisms.

RGs, Biosafety Levels, and Arthropod Containment Levels should be clearly distinguished. RGs describe agent hazards; BSLs and ACLs describe combinations of safeguards selected for particular activities. These systems are not interchangeable, and their numerical designations do not establish equivalent risk or containment. Genetic modification should prompt assessment of its functional consequences, without an automatic assumption that it increases risk.

For gene drive mosquito research, NIH should explicitly recognize the Arthropod Containment Guidelines and their gene drive addendum as complementary to BMBL. Assessment should integrate any pathogen-related hazards with mosquito biology, the modification, experimental procedures, and the consequences of unintended escape in the local environment. A containment requirement should not be interpreted as assigning the mosquito to a corresponding pathogen Risk Group.

To support consistent international implementation, NIH should provide worked examples, a terminology guide, and a crosswalk explaining how relevant BSL and ACL safeguards satisfy policy requirements. Such a crosswalk should compare specific measures rather than imply automatic equivalence between levels. Guidance should also distinguish laboratory containment decisions from the environmental risk assessment and authorization required for deliberate field testing or deployment.

This approach would preserve appropriate safeguards while reducing unnecessary escalation, duplicative facility requirements, and inconsistent interpretation across research institutions and national authorities.

Concept	**What it describes**	**Appropriate role in mosquito research**
Risk Group — RG	An agent's disease-causing hazards, including severity and transmission characteristics.	Relevant to pathogens used in mosquito infection experiments; insufficient to characterize gene drive spread or ecological effects.
Biosafety Level — BSL	A combination of laboratory practices, equipment, and facility safeguards.	Informs controls for infectious materials and laboratory procedures. It is not an intrinsic property of a mosquito.
Arthropod Containment Level — ACL	Practices and facilities tailored to containing live arthropods and associated hazards.	Directly relevant to insectary operations, escape prevention, and the consequences of escaped mosquitoes.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).

NIH should encourage voluntary adoption through practical support, accessible expertise, and recognition of equivalent biosafety arrangements which would need to be assessed. The final policy should distinguish informal adoption of its principles from formal voluntary participation and clearly explain the obligations associated with each. Institutions outside mandatory coverage should be able to understand whether participation entails an Assurance, reporting requirements, or other administrative commitments before enrolling.

NIH should preserve and update the voluntary-compliance mechanisms in Section IV-D of the existing NIH Guidelines, including access to institutional biosafety review, requests for relevant determinations, and procedures for handling proprietary information. Implementation resources, training, and scientific consultation should be available to institutions regardless of their funding source.

For international gene drive mosquito research, voluntary participation should accommodate national legal frameworks, institutional structures, and access to shared or regional expertise. NIH should recognize scientifically justified equivalent safeguards and existing assessments, while retaining consideration of local facilities and environmental conditions. Documentation requirements should be proportionate to the proposed activity and explicit about handling of proprietary information and confidential materials, public disclosure and incident learning information.

Voluntary participation should support institutional capability and confidence in biosafety practice. It should not become an additional authorization requirement for research, collaboration, field testing, or deployment otherwise governed by competent authorities. NIH should also clarify that participation does not constitute product endorsement or environmental-release approval. These measures would encourage broader uptake while avoiding unnecessary duplication and administrative barriers.

Mechanism	How it would encourage participation
Clearly defined voluntary pathway	Explain eligibility, commitments, benefits, and whether adopting guidance differs from formal participation.
Recognition of equivalent oversight	Allow existing institutional and national arrangements to demonstrate comparable biosafety outcomes without recreating a US administrative structure.
Access to guidance and consultation	Make templates, training, interpretation, and scientific advice available regardless of funding source.
Shared IBC and specialist expertise	Help smaller institutions access entomological, ecological, and containment expertise while retaining local accountability.
Proportionate documentation	Accept relevant existing assessments and limit additional information requests to identified gaps.
Clear information protections	Explain handling of confidential submissions, public disclosure, and incident-learning information before participation.

121. Kathleen Brundage

I am responding: On behalf of myself

Name: Kathleen Brundage

Name of Organization: West Virginia University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/6/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support expanding oversight beyond recombinant DNA research to encompass the broader range of biohazards encountered in modern biomedical research. The proposed scope aligns well with the oversight currently conducted by our Institutional Biosafety Committee (IBC) and more accurately reflects the evolving landscape of biomedical research.
However, NIH should provide additional clarification regarding key definitions, particularly those pertaining to Gene Drive Modified Organisms (GDMOs). Clear, consistent, and sufficiently specific definitions will help ensure uniform interpretation and implementation of the proposed oversight framework across institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed risk-based oversight structure is appropriate; however, NIH should carefully evaluate the administrative burden associated with expanded transparency, reporting, and documentation requirements. For smaller biosafety programs, maintaining public websites, publishing meeting minutes and incident reports, and managing Biosafety Assurance requirements may require substantial additional resources. At our institution, these responsibilities would largely fall to a biosafety office consisting of only two full-time professionals. These individuals are also responsible for protocol review, laboratory inspections, training, incident response, risk assessments, and research support. Additional administrative requirements could therefore significantly affect the office's capacity to perform these core biosafety functions.
At a minimum, NIH should provide standardized templates, guidance, and implementation tools and should clearly define the responsibilities of the Authorized Organizational Representative (AOR). Oversight requirements should remain proportional to the level of risk and should be designed to minimize unnecessary administrative burden. Institutional resources should remain focused on essential biosafety activities, including laboratory support, risk assessment, training, inspections, and incident response.

3. Continued utility of Risk Groups: Risk Groups should remain an important component of the risk assessment process, while Biosafety Levels should continue to serve as the primary framework for

determining appropriate containment requirements. Biosafety Level assignments more directly reflect the engineering controls, work practices, and facility features needed to mitigate biological risks.
NIH should continue to encourage institutions to consider agent characteristics, genetic modifications, experimental procedures, and potential exposure pathways when determining appropriate containment. Additional guidance on expectations for establishing, maintaining, and managing microorganism inventories would also be beneficial.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH can encourage voluntary adoption of the policy by developing practical implementation resources, model policies, templates, and training materials. Institutions are more likely to adopt recommended practices when expectations are clearly defined, and implementation is straightforward.
At the same time, transparency requirements should be calibrated to minimize the risk that complex scientific or biosafety information could be misinterpreted by individuals without relevant technical expertise. Clear guidance on the presentation and content of publicly available information could help reduce the potential for public misunderstanding or unnecessary concern

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed templates provide a useful framework; however, NIH should provide additional guidance regarding permissible redactions and the protection of sensitive information, including personnel, grant, and clinical research information.
Public disclosure requirements may also have unintended consequences if researchers perceive that reporting incidents or near misses could result in inappropriate or disproportionate public scrutiny. NIH should therefore consider how reporting and transparency requirements can be structured to preserve incentives for timely and candid reporting.
NIH should also reconsider the proposed 24-hour reporting requirement and allow institutions sufficient time to conduct an initial assessment before submitting a report. Providing a reasonable period for preliminary fact-finding would help ensure that reports are accurate and complete.
In addition, incident reporting should be coordinated through institutional biosafety programs rather than individual investigators. Centralized institutional reporting would promote consistency, accuracy, appropriate documentation, and effective institutional oversight.

6. Other feedback relevant to this resource: Additional guidance will be essential to support successful implementation. Areas that would benefit from further clarification include:
• Definitions and oversight expectations for GDMOs
• AOR responsibilities
• Biosafety Officer qualifications and responsibilities
• Microorganism inventory requirements
• Incident reporting procedures and timelines
• Standards and expectations for publicly posted information
Institutions with limited biosafety staffing will also require practical implementation tools and sufficient time to develop compliant processes. For a biosafety like ours, office staffed by only two professionals, requirements associated with website management, public posting, expanded documentation, and additional reporting obligations may necessitate significant operational changes and could divert resources from direct biosafety oversight activities.
Given the scope of the proposed changes, the six-month implementation period may be insufficient for

institutions to establish compliant processes. NIH should consider providing a longer transition period, accompanied by detailed implementation guidance, standardized templates, and practical tools. This approach would facilitate effective and sustainable compliance while minimizing the potential for implementation requirements to reduce institutional capacity for core biosafety oversight.

Description: The draft policy represents a thoughtful and necessary modernization of biosafety oversight and appropriately expands beyond the historical focus on recombinant DNA research. Successful implementation, however, will depend on clear definitions, practical guidance, realistic implementation timelines, and an appropriate balance between transparency and administrative feasibility. NIH should ensure that new requirements strengthen biosafety oversight without diverting limited institutional resources from the primary objective of identifying, assessing, and mitigating biological risks. This consideration is particularly important for institutions whose biosafety programs operate with small staffs like ours and limited administrative support. Requirements should therefore be designed to achieve meaningful improvements in biosafety oversight while remaining proportionate to institutional capacity and practical to implement. Providing clear expectations, standardized implementation resources, and adequate transition time would help institutions meet the objectives of the policy while preserving the capacity needed to perform essential biosafety functions.

122. Arizona State University

I am responding: On behalf of an organization

Name: Zoë Baker

Name of Organization: Arizona State University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/6/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Arizona State University (ASU) generally supports expanding the scope of the NIH's framework beyond research involving recombinant or synthetic nucleic acid molecules. This expansion is consistent with ASU's existing institutional approach, under which the ASU Institutional Biosafety Committee (IBC) reviews research involving biohazards more broadly. The policy would benefit from greater specificity regarding what research falls within its scope. The draft defines covered research broadly as laboratory biomedical research involving known or potential risks to human health and specified categories of biological materials, while also extending the policy to non-NIH-funded biomedical research conducted at institutions receiving NIH funding. Without additional guidance, these provisions could be interpreted differently across institutions, resulting in potential over-review of low-risk activities and potential gaps in oversight and increased administrative burden at the local and federal levels .

ASU recommends that NIH provide clear examples of both covered and non-covered activities, particularly for primary cells and tissues, blood products, clinical specimens, organoids, microbiome samples, environmental samples, well-characterized cell lines, non-replicating biological materials, and other materials where risk may depend on source and experimental manipulation. NIH should also clarify the treatment of synthetic biology and AI-designed or computationally designed biological agents, including circumstances in which no obvious parent agent exists.

The exclusion of genetically modified plants and plant pathogens that do not cause human disease also warrants additional consideration; although a human-health focused NIH biosafety policy does not need to duplicate USDA or other regulatory frameworks, NIH should clarify how institutions should address genetically modified biological materials that pose ecological or environmental risks.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): ASU generally supports the proposed risk-based structure in which the highest-risk or highest-uncertainty research requires both NIH and IBC approval, most covered research remains under institutional IBC oversight, and specified lower-risk activities may undergo delegated review. This approach appropriately preserves local institutional expertise while reserving federal review for research posing greater risk or uncertainty.

The addition of delegated review is valuable and should help offset some of the burden created by the broader scope of the policy. NIH's proposal currently permits delegated review for activities including RG2 wild-type agents, genetically modified RG1 agents, BSL-1 transgenic organisms, certain low-risk vectors, well-characterized cell lines, and non-Select-Agent toxin proteins. However, additional criteria are necessary to ensure that institutions consistently determine which pathway applies. NIH should provide a decision framework with illustrative examples, clear escalation criteria, and expected review pathways for common research activities. The final guidance should distinguish more clearly among circumstances requiring full IBC review, delegated review, NIH review, or no review.

NIH should also provide expected timelines for federal determinations involving emerging, novel, or zoonotic agents and requests to lower containment. Because research may not begin until required NIH approval is obtained, predictable review timelines will be important to minimizing unnecessary research delays.
The incident provisions should be harmonized across the policy and associated templates. For example, the policy identifies certain animal incidents at BSL-1/ABSL-1 and BSL-2/ABSL-2 as lower-risk events requiring institutional review but not NIH reporting, whereas the draft incident template broadly lists animal bites and scratches among reportable personnel exposures. NIH should resolve such ambiguities and ensure that federal reporting is reserved for incidents of sufficient significance to warrant federal oversight.

3. Continued utility of Risk Groups: ASU supports continued use of Risk Groups (RGs) as an important starting point for biosafety risk assessment. RG classifications provide a useful characterization of the inherent hazards associated with biological agents and facilitate consistent communication across institutions. However, RG classification should not be treated as an automatic determination of the appropriate Biosafety Level (BSL) or Animal Biosafety Level (ABSL). RG and BSL are related but distinct concepts and that appropriate containment depends upon the specific manipulations, genetic modifications, routes of exposure, quantities, procedures, facilities, equipment, personnel expertise, and other experimental conditions involved. ASU recommends retaining both concepts within the final framework: RG as the baseline characterization of inherent agent hazard, followed by an experiment-specific risk assessment that determines appropriate BSL/ABSL containment and additional mitigation measures.

This distinction is particularly important for genetically modified, attenuated, replication-defective, synthetic, or novel biological agents. NIH should provide examples demonstrating how modifications or experimental manipulations may result in containment requirements that are higher or lower than might otherwise be inferred from the parent agent's RG. Guidance for synthetic organisms or constructs with multiple biological sources would also be useful.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): ASU supports the establishment of broadly applicable biosafety principles that can serve as a national model beyond research formally subject to NIH requirements. The draft policy already extends beyond individual NIH-funded projects by applying to biomedical research conducted at institutions receiving NIH funding, irrespective of the specific funding source for the research. NIH should coordinate with other federal agencies and relevant state and local authorities so that institutions are not subject to inconsistent biosafety expectations based solely on

funding source. Broad harmonization of core biosafety principles would be preferable to imposing duplicative or conflicting requirements. NIH should clearly distinguish between mandatory compliance, recommended best practices, and voluntary adoption, so that institutions can understand the legal and administrative implications of each.

For organizations that remain outside the policy's mandatory scope, NIH could encourage adoption through accessible implementation resources, model institutional policies, training materials, risk-assessment tools, and mechanisms through which institutions can voluntarily benchmark their practices against NIH standards.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed incident-reporting and IBC meeting-minutes requirements raise significant concerns regarding proportionality, administrative burden, confidentiality, biosecurity, and the ability of IBCs to conduct candid scientific discussions and safety deliberations.

The draft meeting-minutes template requests detailed project descriptions, experimental manipulations, risk assessments, mitigation strategies, training requirements, occupational health considerations, containment conditions, and other information for each registration. At a large research institution, preparing this degree of detail for public posting could require substantial additional administrative and technical effort. NIH should focus required public minutes on information necessary to demonstrate that the IBC appropriately evaluated risk and fulfilled its oversight responsibilities rather than requiring detailed reconstruction of the underlying protocol.

ASU recommends that NIH provide clearer and more protective rules for sensitive discussions and information. Institutions should be explicitly permitted to enter a closed or executive session when necessary to discuss proprietary, security-sensitive, personnel-related, occupational-health, or other appropriately confidential matters. Public minutes could document that such a discussion occurred, its general purpose, and any resulting IBC action without disclosing protected details.

The proposed redaction standards should be revised. The templates acknowledge that proprietary, private, and security-sensitive information may be redacted, but also state that information available elsewhere—including biological agents used in research, including Select Agents—generally may not be redacted. NIH should permit institutions to evaluate information in context: the aggregation of individually public facts may create meaningful security, proprietary, or research-integrity concerns.

Similarly, incident reporting should be risk-proportionate. The policy should clearly distinguish incidents requiring NIH reporting and public posting from lower-risk events managed locally. NIH should consider a streamlined institutional record for low-risk incidents rather than requiring the same reporting structure used for more consequential events. Public reporting should provide sufficient context to reduce the likelihood that routine or appropriately managed incidents are misleadingly interpreted as evidence of unsafe research practices.

Transparency requirements should be designed so that they do not inadvertently discourage timely incident reporting or candid discussion by investigators and IBC members. A strong safety culture

depends on open reporting of errors, near misses, and concerns without creating unnecessary reputational disincentives.

6. Other feedback relevant to this resource: Substantial implementation guidance will be essential before the new policy becomes effective. Consistent implementation will depend upon institutions having detailed, practical resources.

ASU recommends that NIH prioritize guidance addressing:
- Decision trees and examples distinguishing covered, non-covered, and potentially exempt low-risk research
- Criteria and examples for full IBC review, delegated review, NIH review, and activities requiring no review
- Treatment of primary cells and tissues, clinical specimens, blood products, organoids, microbiome and environmental samples, well-characterized cell lines, and non-replicating biological materials
- Synthetic biology, AI-designed biological systems, and novel agents for which conventional RG classification may be difficult
- Ecological and environmental risks and the relationship of the NIH policy to other federal oversight frameworks
- Experiment-specific use of RG classifications and BSL/ABSL determinations
- Thresholds and examples for NIH-reportable versus institutionally managed incidents
- Appropriate redaction standards, treatment of sensitive information, and use of closed/executive IBC sessions
- Standardized but proportionate approaches to meeting minutes and incident reporting
- Coordination among IBCs, IRBs, IACUCs, occupational health programs, environmental health and safety programs, and other institutional oversight bodies where responsibilities overlap.

Given the expansion in scope, development of new institutional procedures and assurances, changes to electronic systems, training needs, and increased administrative responsibilities, ASU encourages NIH to evaluate whether a longer or phased implementation period would better support consistent and effective compliance.

123. Ericka Pearce

I am responding: On behalf of myself

Name: Ericka Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/6/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Scope of Genetically Modified Organisms

I support NIH's goal of ensuring appropriate oversight of emerging biotechnology and genetically modified organisms. However, the proposed scope provision covering "cells, viruses, or organisms, other than plants, that have been genetically modified" may unintentionally expand IBC oversight to a broad range of routine, low-risk research activities.

As written, the definition of genetic modification includes nucleic acid molecules that "can be transcribed or translated," potentially encompassing common molecular biology tools and models such as expression vectors, reporter constructs, commercially available modified cell lines, transgenic animals, and CRISPR-edited cells with well-characterized risk profiles.

Having reviewed countless protocols over the course of my career, my concern is not whether genetically modified materials warrant oversight, but whether oversight should be triggered by the presence of a genetic modification alone rather than by the risks associated with that modification.

Operational Impact

A broad interpretation could substantially increase the number of protocols requiring review, lengthen review timelines, and divert limited biosafety resources away from higher-risk activities. The timing of this proposal further compounds these challenges, as institutions are simultaneously implementing other significant federal oversight initiatives related to biosecurity and high-consequence life sciences research.

Recommendation

NIH should clarify whether oversight is intended to be triggered by the presence of a genetic

modification or by the biosafety and biosecurity risks associated with that modification. I encourage NIH to adopt a risk-based approach and consider exclusions for common, low-risk molecular biology tools, established research models, and commercially available reagents. Oversight should be commensurate with risk rather than modification status alone.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

124. Perla J. Rodriguez

I am responding: On behalf of myself

Name: Perla J. Rodriguez

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Senior Safety Analyst - support and manage our IBC

Date Submitted: 10/7/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Translational Medicine

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am submitting these comments in my individual capacity. The opinions expressed are my own and do not represent the views of my employer.
The proposed expansion of oversight to all biomedical research involving biohazards is understandable; however, several core definitions remain insufficiently specific to support consistent institutional implementation.
Additional clarification is needed regarding:
• The definition of "biomedical research."
• The meaning of "potential risk to human health."
• The intended scope of "biohazards."
• Activities that are regulated versus operational or clinical in nature.
Specific research activities that would benefit from clarification include:
• Human-derived materials with unknown infectious potential.
• Clinical specimens collected for research purposes.
• Environmental and wastewater surveillance samples.
• Microbiome research.
• Biobanking activities.
• Attenuated or replication-defective systems.
• Research involving non-pathogenic genetically modified organisms.
• Emerging synthetic biology applications.
The broad definitions may result in considerable variability in how institutions determine what requires IBC review. NIH should consider developing a scope determination guide or decision tree containing examples of included and excluded activities, similar to how the current NIH Guidelines use experiment categories to establish oversight expectations.
Additionally, while the policy expands oversight substantially, there remain potential gaps related to research involving emerging biological technologies, AI-enabled biological design, and novel biological

systems that may not fit neatly within traditional risk classifications. Additional guidance on these areas would be beneficial.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed tiered oversight structure is conceptually appropriate and aligns with the principle that oversight should be commensurate with risk. However, several aspects of the federal-local oversight relationship require clarification.

The draft significantly expands IBC responsibilities while providing limited guidance regarding:

- Institutional authority versus IBC authority.
- Delegated review processes.
- Administrative review mechanisms.
- Accountability for risk determinations.
- Roles and responsibilities within centralized or externally administered IBC models.
- Processes for resolving disagreements regarding risk assessments.

The policy would benefit from a clearly defined governance framework that describes which decisions belong at the institutional level versus the federal level and how local discretion should be exercised.

The draft also introduces a number of circumstances requiring NIH consultation or approval. Additional guidance should be provided regarding expected timelines for NIH review and how institutions should manage research activities pending federal determinations.

For multisite research, NIH should consider whether centralized or single-IBC models may be appropriate for certain types of studies, similar to the single-IRB approach used for human subjects research. Such models could reduce duplicative review while maintaining appropriate oversight.

3. Continued utility of Risk Groups: Risk Groups continue to provide value as a foundational risk assessment tool; however, they should not be used as the sole determinant of containment requirements.

The current NIH Guidelines appropriately recognize that risk assessment involves multiple factors in addition to RG classification. These factors include:

- Host range.
- Route of exposure.
- Experimental manipulations.
- Availability of prophylaxis or treatment.
- Animal model considerations.
- Genetic modifications.
- Environmental risks.

The proposed policy emphasizes independent risk assessment by institutions and IBCs, yet does not provide a standardized methodology for performing those assessments.

NIH should consider developing:

- Standardized risk assessment templates.
- Examples of completed risk assessments.
- Decision trees linking RGs, BSLs, and experimental factors.
- Guidance regarding acceptable documentation standards.
- Case studies involving genetically modified organisms and novel agents.

RGs remain useful as a starting point; however, BSL assignments and containment decisions should continue to be driven by a holistic risk assessment framework rather than RG classification alone.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Encouraging adoption beyond NIH-funded institutions is an important objective. Voluntary compliance is most likely to occur when the policy is practical, clearly written, and supported by implementation resources.

NIH could encourage broader adoption by providing:

- Model institutional policies.
- Risk assessment templates.
- Training materials.
- Frequently asked questions.
- Example workflows.
- Sample committee procedures.
- Publicly available educational resources.

The policy should be viewed as a framework that institutions can realistically implement rather than solely a regulatory requirement.

The success of voluntary compliance will also depend on maintaining reasonable administrative burden. Institutions are more likely to adopt the framework if requirements are clearly risk-based, scalable, and supported by practical tools.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed emphasis on transparency is commendable and likely to strengthen public trust in research oversight. However, several aspects of the reporting and public posting requirements would benefit from clarification.

Incident Reporting:

Several reporting triggers remain open to interpretation, including:

- "Potential laboratory-acquired infection."
- "Potential community risk."
- "Potential release."
- "Significant risk to human health."
- "Agent-specific treatment."

More objective reporting thresholds would help ensure consistency among institutions and reduce the potential for both under-reporting and over-reporting.

NIH should consider publishing:

- Reportability decision trees.
- Case studies.
- Frequently encountered examples.
- Reporting threshold guidance.

In addition, expanded reporting and public disclosure requirements should be carefully balanced against maintaining a strong institutional reporting culture. Effective biosafety programs depend on the willingness of personnel to report incidents, near misses, and lessons learned. Requirements should be structured to encourage transparency and continuous improvement rather than create perceived disincentives to reporting.

Meeting Minutes

Additional guidance is needed regarding:

- Appropriate levels of detail.
- Protection of proprietary information.

• Protection of intellectual property.
• Protection of unpublished scientific findings.
• Patient privacy considerations.
• Information that could create biosecurity concerns.
Standardized redaction guidance and sample meeting minutes would help institutions implement these requirements consistently.

6. Other feedback relevant to this resource: The following resources would be particularly valuable:
Transition Resources
• Formal crosswalk between the current NIH Guidelines and the proposed oversight structure.
• Grandfathering guidance for active protocols.
• FAQs regarding implementation.
• Examples of compliance expectations during transition.
Governance Resources
• Guidance on IBC authority and delegation.
• Model governance frameworks.
• Examples of centralized and shared IBC models.
Clinical Research Resources
Additional guidance is needed regarding:
• Gene therapy studies.
• Cellular therapy studies.
• Shedding assessments.
• Clinical administration of biohazardous products.
• Multisite clinical studies.
• Coordination among IBCs, IRBs, clinical research personnel, and study teams.
The policy should also address how biosafety expectations apply in clinical environments that do not operate under traditional BSL frameworks, such as:
• Outpatient infusion centers.
• Inpatient units.
• Pharmacies.
• Clinical specimen processing areas.
Coordination with Other Oversight Programs
Additional guidance should clarify how responsibilities should be coordinated among:
• IBCs.
• IRBs.
• IACUCs.
• Occupational Health Programs.
• Environmental Health and Safety Offices.
• Institutional incident management programs.
Without clear delineation of responsibilities, there is potential for duplicative review and administrative burden without corresponding improvements in safety.
Institutional Assurance Resources
The proposed Institutional Biosafety Assurance program represents a substantial new obligation.
Additional guidance should clarify:
• NIH review timelines.

• Approval and renewal processes.
• Required updates between renewal cycles.
• Implications of delayed approvals.

Implementation Timeline

Finally, many institutions will need significant time to update policies, train personnel, revise systems, establish assurance processes, and adjust committee operations.

Given the breadth of the proposed changes, NIH should consider whether a six-month implementation period is sufficient and evaluate the benefits of a phased implementation approach supported by transition guidance and outreach activities.

Conclusion

Overall, I support NIH's effort to modernize biosafety oversight and establish a comprehensive framework that reflects contemporary biomedical research. The areas most in need of additional clarification are: (1) scope and definitions; (2) governance and authority; (3) standardized risk assessment expectations; (4) clinical research oversight; (5) incident reporting and transparency requirements; and (6) implementation resources and transition planning. Addressing these issues prior to finalization will improve consistency, reduce institutional variability, and enhance successful adoption of the policy across the research community.

125. Cleveland Clinic

I am responding: On behalf of an organization

Name: blair barnhart-hinkle

Name of Organization: Cleveland Clinic

Type of Organization: Healthcare Institution

Role: Organizational Official

Date Submitted: 10/7/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cleveland Clinic

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Draft NIH Biosafety Policy for Research Involving Biohazards demonstrates the NIH's firm commitment to ensuring that all work performed at NIH funded institutions is done safely. Updated guidance regarding transparency helps to assure surrounding communities that scientific breakthroughs are not coming at the expense of public interest. We appreciate this opportunity to comment and offer feedback that we hope will further both the ideals presented in these documents as well as those of the NIH as an institution.

The draft policy substantially expands the scope of activities requiring Institutional Biosafety Committee (IBC) oversight beyond recombinant or synthetic nucleic acid molecule research to include biomedical research involving known or potential biohazards. This would impose a significant regulatory and administrative burden on both investigators and institutional biosafety programs by requiring registration of routine, low-risk research materials and activities. As currently framed, the policy could require principal investigators to individually register every gene target, well-characterized cell line, plasmid, transgenic organism cross, and similar research material, even when the work is conducted at Biosafety Level 1 (BSL-1) or Animal Biosafety Level 1 (ABSL-1). Requiring IBCs and biosafety offices to triage a much larger amount of low-risk research could lengthen review timelines and consume committee and administrative resources. This could dilute attention from higher-risk research, incident follow-up, facility-specific biosafety concerns, and substantive biosafety program oversight.

NIH should identify categories of low-risk research, or protocol amendments, that may be excluded from formal oversight – or at most acknowledged or registered at the institutional level – to avoid unnecessarily expanding oversight. Although the draft policy contemplates delegated review, it does not clearly specify the level of review required for those determinations. If review and approval is required for routine low-risk activities, such as transient transfections, transgenic organisms without hazardous gene expression etc., or Risk Group 1 modifications that do not present a credible biosafety concern, oversight should not go beyond knowing that these general categories of work are occurring in a laboratory and ensuring that appropriate risk-based containment, facilities, training, and safety practices

are in place. It should not require detailed activity-by-activity review. Activity- by-activity review, whether it is delegated or full committee review, should be reserved for higher-risk agents, hazardous modifications, or work involving uncertainty where substantive review is necessary to ensure safety. Furthermore, additional information would be required to identify the scope of review needed for clinical studies and transgenic animals. Ideally, transgenic animals not considered Gene Drive Modified Organisms (GDMOs) or modified only to express low-risk transgenes should be exempt from IBC review due to the low risk of the associated modification to the handler and the environment

Below are some examples of minimal biosafety risk that should be excluded:
1. Use of research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes in tissue culture (e.g. simple gene overexpression or knock down in tissue culture in which infectious agents, toxins, or other hazardous gene products).
2. Research with well-characterized cell lines used in combination with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low risk transgenes in tissue culture at BSL1 or BSL2, where infectious agents, toxins or other hazardous gene products are not anticipated to be present or produced.
3. Research conducted with transgenic organisms at BSL1/ABSL1 containment.
4. Research with K-12 E. coli to perform DNA amplification and purification at BSL1.
5. Research with non-K12 E.coli to perform protein expression and purification at BSL1, where toxins are not produced.
6. Research with the expression of non-toxic B subunit of toxins only, in which the active, toxic component (A subunit) is not present.

If the agency does not exclude these activities, we recommend a requirement to ensure that review of general categories of work and appropriate containment and safety measures are in place.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The draft policy appropriately identifies categories of research that require both NIH and IBC approval prior to initiation. This approach is particularly valuable for emerging, novel, or otherwise unclassified agents, where centralized review can promote consistency in risk assessment and containment recommendations across institutions. We support this aspect of the framework as a means of improving standardization and reducing variability in oversight. Nonetheless, concerns remain regarding the time required for NIH assessment and approval, particularly when research involving emerging or novel pathogens may be urgently needed to inform public health responses, characterize newly identified agents, or to develop diagnostics, therapeutics, and vaccines. Consideration should be given to establishing defined review timelines or expedited review pathways for time-sensitive research while maintaining appropriate biosafety oversight.

While the scope of the proposed policy expands beyond recombinant DNA research to encompass a broader range of biohazards, the majority of research activities would continue to be reviewed at the local level, which we believe is appropriate and allows institutions to apply site-specific expertise, facilities knowledge, and operational considerations to the oversight process. While centralized NIH review is available for research where there is no standard, concerns remain regarding the continued local review of activities that present minimal biosafety risk. Requiring protocol-specific review of routine, low-risk research, with a policy that significantly expands the scope of review, may impose

substantial administrative burden without a commensurate biosafety benefit. Clear exclusion criteria and expanded use category-based review for well-defined low-risk activities would allow institutional resources to be focused on research with meaningful biosafety implications.

3. Continued utility of Risk Groups: An initial classification of a biological agent is a useful starting point for biological risk assessment because they categorize agents based on known characteristics. However, an agent's risk can change substantially when genetic modifications are introduced, or they are used in high concentrations. Biosafety Levels (BSLs), when assigned through a comprehensive risk assessment, are often more useful for determining the actual risk of the final material and the containment needed for the specific work being performed.

This distinction is already evident for many emerging vector-borne viruses. These viruses are classified as RG2 but are routinely handled at BSL-3 because of factors such as aerosol transmission potential, limited medical countermeasures, uncertainty about pathogenicity, or the procedures being performed. Even without genetic modification, containment requirements may exceed what researchers expect based solely on RG classification. While experienced biosafety professionals generally understand this distinction, it can be confusing for junior biosafety professionals, investigators, and new researchers. The terminology can also be misleading because an assigned "Risk Group" does not necessarily reflect the actual "risk" to the use of a biological agent or translate directly to the appropriate containment level.

Having an initial reference point for evaluating a pathogen before considering additional factors such as agent characteristics, proposed modifications, procedures, and containment practices is beneficial. To reduce confusion, NIH could consider terminology that more clearly distinguishes an agent's baseline classification from the final risk-based containment determination of BSL. Examples might include "Initial Agent Hazard Group," or "Starting Risk Classification" in place of "Risk Group." This type of nomenclature would reinforce that this initial classification informs the assessment of what biosafety level to work at but does not independently determine the appropriate biosafety level.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): For entities not receiving federal funding, consideration should be given to requiring compliance with NIH biosafety standards, or equivalent recombinant DNA oversight requirements, as a condition for future federal funding, regulatory review, or advancement of products through later stages of development. For example, companies conducting research without federal funds could be expected to demonstrate adherence to NIH recombinant DNA and biosafety requirements, or equivalent standards, when seeking FDA approval or advancing products through later stages of development. This would promote consistent biosafety practices across the research and product development pipeline.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The updated meeting minutes template and additional clarifications regarding the public meeting minutes will be helpful in drafting the document, but as written, the guidance suggests the draft template is the required format and implies institutions are asked to list every organism and manipulation. It is not unusual for the IBC to review multiple protocols a month that include over 100 individual bacteria, viruses, and cell lines. While the Committee reviews each item, and they are documented in the IBC protocol, repeating that information in the minutes would expand them to a size where it would be offering no clarity for local communities.

While the meeting minutes should mention all items that fall under the policy, being able to group certain items or lower risk agents under general categories or allowing institutions to adapt the template would be appreciated. For example, if a lab is overexpressing oncogenes in 30 Risk Group (RG) 2 human cell lines with 10 different viral vectors; instead of listing all 40 items individually, this could be accomplished with, “Oncogenes may be overexpressed in human cell lines using replication defective viral lentiviral vectors. Experiments are performed at BSL-2.”

Although incidents are now required to be made publicly accessible on institutional websites, we recommend that the Annual Incident Summary Report should preserve institutional anonymity where appropriate to avoid unintentionally identifying, targeting, or misrepresenting a single institution. This is particularly important when the annual report may not include sufficient detail regarding the circumstances of the incident, its context, corrective actions, and final resolution.

6. Other feedback relevant to this resource: While the draft policy will be an enormous step forward in safety and transparency for NIH funded research, we urge NIH to consider allowing a timeframe (4-6 months) between release of final policy and start of implementation for institutions to devise and implement new training and documents. Ideally policy implementation would also occur over an extended period (6-8 months) as well to ensure all applicable research is accurately identified, reviewed, and approved.

Additionally, we would appreciate clarification on the following items:
• GDMOs: Examples of currently used applicable techniques would be appreciated, along with a definition of what is meant by “organism”. Furthermore, does this reference sexually reproducing multicellular organisms only or are lower-level organisms included as well (bacteria, viruses, tissue culture, etc.).
• Well Characterized Cell Lines: Specific criteria would be appreciated. We propose well-characterized cell lines would include that the cell line had no known infection at time of acquisition, has not been exposed to an infectious agent after acquisition, are either non-recombinant modified or have only been modified to express low-risk transgenes, such as GFP, and are screened for common bloodborne pathogens. We recommend that this work be excluded from routine review or, at most, require a brief description of the general category of research. This would allow verification that appropriate biosafety practices, containment measures, and institutional safety protocols are in place, rather than necessitating an itemized review of individual cell lines meeting the above criteria. This approach would ensure that oversight remains consistent with the scope and intent of the policy, focusing on safety and compliance without creating unnecessary administrative burdens for research activities that present minimal biohazard risk.
• Low-risk Transgenes: Criteria for what would be considered a low-risk transgene would be appreciated. We propose that low-risk transgenes should include fluorescent tags and antibodies, transgenes not considered oncogenes or tumor suppressor genes, transgenes produced by non-pathogenic organisms, and transgenes that have no known causative role in disease. Additional guidance on the distinction between low-risk and hazardous gene products would improve consistency across institutions and help focus IBC review on research with substantive biosafety risks rather than routine tissue culture applications. We recommend that this work be excluded from routine review or, at most, require a brief description of the general category of research. This would allow verification that appropriate biosafety

practices, containment measures, and institutional safety protocols are in place, rather than necessitating an itemized review of individual genes meeting the above criteria. This approach would ensure that oversight remains consistent with the scope and intent of the policy, focusing on safety and compliance without creating unnecessary administrative burdens for research activities that present minimal biohazard risk.

• Section IV-2: As we understand the categories for IBC regulated clinical trials, this would exclude work with some mRNA therapies from IBC review, as they are generally non-integrating and don't shed or replicate. We urge NIH to clarify whether this is the correct interpretation, or if any therapy that results from expression of an exogenous protein (i.e. mRNA that results in expression of a viral protein for a vaccine) is under IBC purview.

• DNA segments Risk Group 3 and 4 agents: We suggest NIH clarify whether institutions must petition the NIH to determine the appropriate biocontainment level for experiments in which DNA from Risk Group 3 or 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes, in which an infectious agent is not anticipated to be produced (e.g. single viral gene expression) If the IBC or delegate identifies the risk to be low, we recommend approval at the Institutional level.

• Room Amendments: We suggest NIH clarify the process for approving new locations of work for previously approved procedures. We recommend that approval of room changes be explicitly included in Section IV-3 (Delegation), enabling each institution to determine whether such approvals may be handled by the Biological Safety Officer (BSO), a designated subgroup of IBC members, or referred to the full Institutional Biosafety Committee for review. This flexibility would allow institutions to align review pathways with the complexity of their facilities and the nature of the proposed changes, ensuring that modifications warranting comprehensive evaluation are brought before the full committee, while routine or lower-risk changes can be managed quickly and efficiently through delegated review.

• Delegated Review Requirements: We urge the NIH to clarify whether institutions may establish, at their discretion, criteria for determining which amendments qualify as eligible for delegated review versus those requiring full IBC review.

We appreciate NIH's efforts to modernize biosafety oversight and develop a framework that is risk-based, scalable, and adaptable to emerging technologies. Given our institution's extensive experience in biosafety, recombinant and synthetic nucleic acid research oversight, high-containment research, animal research, and implementation of institutional biosafety programs, we would welcome the opportunity to participate in future working groups, advisory committees, stakeholder discussions, or pilot implementation efforts related to this policy. We would be happy to serve as a subject matter resource to NIH as the policy and associated guidance documents are refined to ensure they are both scientifically rigorous and practical to implement across diverse research environments.

126. Tanya Herzog

I am responding: On behalf of myself

Name: Tanya Herzog

Name of Organization: Houston Methodist Research Organization

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/7/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer and neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As written, the scope would cover all biomedical research using animals since every animal possesses wide-type biological agents that can cause disease in humans. In section IIIB, the draft policy states that exposures due to adventitious agents, such as from an animal bite, not deliberately involved in the research are excluded from reporting. Please clarify if the policy only covers research in which agents are deliberately administered to humans or animal.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The language on the incident report is very vague, and appears to cover every scenario in which an individual in injured in an animal facility. For example "Any incident at BSL-1/ ABSL-1 that does not involved agent specific medical treatment when first aid is administered" implies that any slip, fall or accident that occurs in the vivarium needs to be reported to the IBC. Since the stated purpose is to reduce "red tape" for low risk research, both the scope of what is covered by the policy needs to be clarified.

6. Other feedback relevant to this resource: N/A

127. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/8/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Will the citations/sections previously built into the NIH Guidelines be incorporated into the new policy? Or is this now a more subjective risk assessment process?

Why are plants specifically omitted? Are there no concerns for ecological (e.g., crop) impact?

For research that must be reviewed by the IBC, must the review take place at a convened meeting with a quorum of members?

It would be preferable if the new NIH policy only applied to federally funded research (similar to NIH oversight of animal research). The involvement of an assurance (like for animal research) should also be limited to federally-funded work (unless an institution decides to increase the scope).

Does the new policy apply to biosafety in instruction (e.g., undergraduate coursework) or just in "research"?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

128. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/8/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): virology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Draft NIH Biosafety Policy for Research Involving Biohazards is not ready for implementation. Replacing a framework developed and refined over decades requires a policy that is at least as operationally coherent, technically complete, and administratively workable as the framework it supersedes. This draft is not. It expands institutional jurisdiction dramatically—including to non-NIH-funded research at any institution receiving NIH funds—while replacing much of the current Guidelines' specificity with broad definitions, incomplete categories, undefined terms, and requirements whose practical consequences have not been adequately resolved.

The current NIH Guidelines are often overly detailed, use confusing terminology, and contain provisions that can be difficult to reconcile. Those shortcomings warrant modernization. The proposed replacement, however, overcorrects: it is simultaneously too sparse to guide consistent decisions and too broad to permit proportionate implementation. Core requirements are deferred to future supplemental materials even though institutions would have only six months to bring new and ongoing research into compliance. A complete overhaul should not be finalized until the operative guidance, templates, examples, decision rules, and implementation resources are available for public review as an integrated package.

"Gold-standard" language
The repeated assertion that NIH will ensure "gold-standard science" under "gold-standard biosafety conditions" should be stricken. The phrase is tacky, self-congratulatory, and reads as propaganda rather than technical policy. "Gold standard" has no defined operational meaning here and adds nothing to the enforceable requirements. A federal biosafety policy should state measurable objectives—safe, proportionate, evidence-based, consistent, and adaptable oversight—rather than rely on promotional slogans.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The draft greatly expands the number and variety of activities requiring review while simultaneously increasing IBC documentation, monitoring, reporting, posting, and assurance obligations. It extends the policy to wild-

type RG2 agents, genetically modified cells, primary cells that may contain adventitious agents, toxins, prions, and covered non-NIH-funded work at NIH-funded institutions. It also requires de novo review at least every three years, periodic compliance review, reporting of delegated approvals at the next meeting, NIH petitions in uncertain cases, and use of mandatory templates.

This is an unfunded mandate of substantial scale. NIH has not demonstrated that institutional IBCs—or NIH itself—have the staffing, subject-matter breadth, administrative support, and review capacity necessary to implement it without delaying research or diverting attention from higher-risk oversight. Requirements that consume committee attention indiscriminately can reduce safety by obscuring the relatively small subset of activities that warrants intensive scrutiny.

NIH should conduct and publish an administrative-burden analysis before finalization. The final policy should authorize proportionate mechanisms such as documented exemptions, notification-only categories, staff or biosafety officer review, delegated review, approved institutional risk matrices, umbrella protocols for recurring low-risk work, and clear amendment thresholds. Delegated review should not require reproducing every low-risk approval in public-facing committee records; a concise docket would be more proportionate.

The draft properly recognizes that both the agent and the proposed manipulations matter. The BMBL likewise treats protocol-driven risk assessment as its core principle and explicitly cautions that no single document can enumerate every combination of hazards and mitigations. The problem is not experiment-specific risk assessment itself; it is the draft's failure to establish a workable division of labor and appropriate level of granularity. The PI should retain primary responsibility for experiment-level risk assessment, selection of practices and containment within the boundaries of an approved protocol, personnel training, and day-to-day implementation. The IBC should independently review the PI's assessment, approve agents and defined classes of manipulations, set containment floors and conditions, and examine material changes or unusually hazardous experiments. It should not be necessary for the full IBC to separately reconstruct and document the risk assessment for every assay, minor procedural variant, or routine experiment conducted by a large laboratory. The current Guidelines already assign the PI the initial containment determination and require independent IBC assessment; the replacement should preserve and clarify that allocation rather than blur operational ownership.

The policy should therefore distinguish among:
• Project-level approval: agents, constructs, broad activity classes, facilities, personnel qualifications, and containment boundaries.
• PI-controlled experiment-level implementation: specific procedures that remain within the approved risk envelope.
• IBC re-review triggers: changes reasonably likely to alter hazard, exposure probability, consequence, containment, occupational-health needs, environmental risk, or the validity of previously relied-upon mitigation.
• NIH review: genuinely novel or high-consequence questions that cannot be resolved using established agents, parent-agent classifications, published precedent, or defined federal decision rules.

The draft requires re-review of changes that have a "potential impact on the original biosafety

assessment," but that phrase is too indeterminate to support consistent compliance. Almost any procedural change could be said to have some potential impact. NIH should define materiality and provide examples of changes that do and do not require prospective re-review. Re-review should be limited to changes reasonably likely to alter hazard, exposure probability, consequence, containment, occupational-health needs, environmental risk, or the validity of previously relied-upon mitigation. Changes that remain within previously approved containment, agent, construct, procedure, scale, and exposure parameters should be handled through institutional amendment pathways without mandatory full IBC re-review.

3. Continued utility of Risk Groups: The policy's stated scope lacks internal coherence. It invokes risk to humans and the environment, defines "biological agent" as an organism that causes human disease, excludes plants, and addresses zoonotic agents, animal prions, gene-drive organisms, and environmental risk without presenting a coherent One Health framework. NIH should state expressly how the policy interfaces with USDA APHIS, the Federal Select Agent Program, EPA, FDA, and other federal authorities for plant pathogens, animal-only pathogens, zoonotic agents, agricultural agents, and agents with uncertain host range. The clause allowing work under another federal agency's oversight does not explain which regime controls when jurisdiction overlaps, when another agency's review is narrower, or when an animal or plant pathogen is being developed as a vector, vaccine platform, or oncolytic agent for human use. Risk should be based on the properties and intended use of the material, not solely on whether the parental organism is conventionally labeled a human, animal, or plant pathogen.

The definition of "biohazard" for scope purposes depends on "known or potential risk to human health," but that phrase is undefined. Without a threshold of plausibility and consequence, the policy could sweep in an enormous range of materials for which any human-health nexus is merely theoretical. NIH should define the required nexus to human health and distinguish credible biological risk from speculative possibility.

The definition of "emerging agent or organism" is scientifically nonstandard and too narrow. Emerging infections commonly include diseases that newly appear in a population or are increasing in incidence or geographic range. Zika virus illustrates the problem: it was first isolated in 1947 but caused its first recognized epidemic in 2007 and later expanded dramatically in geographic range. The definition should encompass newly recognized agents, known agents exhibiting materially changed epidemiology or phenotype, and known agents entering new populations or ranges.

The definition of "novel agent or organism" is also insufficiently defined. As written, it could be read to encompass ordinary engineered mutants without distinguishing them from substantially redesigned or genuinely unprecedented agents. NIH should specify whether "novel" requires the absence of an established parent-agent risk classification, a materially new phenotype, a substantial genomic redesign, or uncertainty that cannot be resolved through ordinary institutional risk assessment.
The petition requirements are also disproportionate and appear skewed toward attenuation or loss-of-function examples. Many modifications are neutral, incompletely characterized, or intended to add a laboratory function such as reporter expression. NIH should request only information material to the containment decision and should offer abbreviated petitions based on parent-agent precedent, construct class, and validated institutional risk assessment.

Modern virology and vectors

The policy does not provide an operational framework adequate for modern virology. It should distinguish, with examples and decision criteria, among genetically modified replication-competent viruses, replication-defective viruses, single-cycle viruses, viral vectors, pseudotyped particles, virus-like particles, helper-dependent systems, producer cells, packaging systems, trans-complementable replicons, and infectious clones. It should also address the probability and consequences of recombination, complementation, mobilization, replication-competent revertants, altered tropism, and rescue in trans. The current NIH Guidelines expressly address defective viruses in helper systems and the possibility of generating replication-competent virus; the replacement policy should not discard that operational clarity. Terms such as “replication-incompetent,” “non-integrating,” “reporter,” “low-risk transgene,” and “well-characterized cell line” require definitions or decision criteria. A vector can be replication-incompetent yet still present meaningful hazards related to transduction, insertion, mobilization, expression product, pseudotype, or accidental complementation.

Clinical research

The category for clinical administration should be clarified with worked examples. “Capable of shedding, replicating, or integrating” is not sufficiently precise and may be interpreted inconsistently across self-amplifying RNA, genetically modified cells, integrating-vector products, non-replicating viral vectors, and oncolytic viruses. The policy should classify CAR-T and other genetically modified cell products, self-amplifying RNA, AAV-mediated gene delivery, non-replicating viral vaccines and vectors, oncolytic viruses, bacteriophage products, microbiome products, and products for which only residual vector components may be detectable. Risk categories should focus on occupational and environmental biosafety questions that are within IBC expertise: preparation and administration, sharps and aerosol risks, replication competence, shedding, contacts, waste, spill response, and environmental release. The policy should also explain the endpoint of IBC oversight for long-lived or integrating products rather than presuming that the last administered dose is generally an adequate endpoint.

Wild-type RG2 agents

The draft appropriately requires review and approval for research involving wild-type RG2 biological agents, but it does not adequately explain why all such work should require prospective approval rather than a mixture of notification, standing institutional controls, delegated review, and full review based on manipulation and context. The final policy should make clear that antimicrobial-resistance phenotype, transmissibility, available countermeasures, route of exposure, concentration, scale, and procedure hazards can elevate a wild-type RG2 project. Conversely, routine work with well-characterized RG2 organisms under standard research conditions should not consume the same review resources as work involving enhanced resistance, aerosol generation, large scale, animal transmission, or altered host range.

Influenza provisions

The continued exceptional treatment of influenza should either be justified by a generalizable risk

principle or replaced with phenotype- and consequence-based rules applicable across virus families. A segment-counting rule is an inadequate surrogate for risk because a minority of segments can materially alter receptor use, replication, host range, antigenicity, drug susceptibility, or transmission. At a minimum, the policy should require the higher applicable starting containment when any segment derives from a higher-risk parent, followed by a documented risk assessment that considers the identity and function of each segment, substitutions, constellation effects, phenotype, and available empirical data. Any reduction should be based on evidence and precedent, not simply on which parent contributed the majority of segments.

Cells and primary materials

Section IV-2 appears to require IBC review for genetically modified cells, yet the scope language suggests that covered materials should also present a known or potential risk to human health. NIH should clarify whether all genetically modified cells are in scope or only those presenting a credible biosafety risk. Routine modifications of established human cell lines frequently do not materially increase biosafety risk. NIH should create an exemption or notification category for modifications that do not introduce an infectious, toxic, oncogenic, mobilizable, integrating, or otherwise hazardous function and that do not alter susceptibility in a way that creates a material hazard.

“Primary cells that may be contaminated by adventitious agents” is similarly overbroad because, absent adequate testing and provenance, most primary human or animal cells may harbor adventitious agents. NIH should distinguish established screened commercial sources; human materials already addressed through occupational bloodborne-pathogen frameworks; nonhuman-primate materials; cells from species associated with specific zoonoses; cells intentionally exposed to agents; and materials with epidemiologic or diagnostic indications of infection. Full IBC review of every use of untested primary cells would be disproportionate.

Cell-free nucleic acids

The draft does not adequately address hazardous nucleic acids before their introduction into a cell or organism. Infectious viral genomes, full-length infectious clones, and nucleic acids complexed with lipids or other delivery systems can present meaningful risk even while cell-free. The policy should explicitly cover cell-free nucleic acids when they are inherently infectious, encode a regulated or high-consequence product, constitute a substantially complete infectious genome, or are formulated or manipulated to facilitate cellular entry. Risk categories should account for genome polarity, need for helper functions, delivery vehicle, route of exposure, stability, quantity, and the plausibility of initiating infection or toxic expression. The policy should be harmonized with Federal Select Agent regulations, which expressly cover nucleic acids capable of producing infectious forms of select-agent viruses and certain nucleic acids encoding regulated toxins.

Selection and enrichment

It is appropriate that the concept of genetic modification is not limited to conventional molecular cloning and includes stable changes introduced through passaging, reassortment, chemical treatment, or

radiation. The framework should go further and address selection or enrichment processes that materially change the hazard of a population without necessarily creating an additional genetic change during the research. For example, isolating and expanding an antibiotic-resistant subpopulation from a heterogeneous clinical specimen can greatly increase concentration, purity, and exposure consequence even if the resistance determinant was already present. Similar concerns arise when selecting host-range variants, enriching preexisting escape mutants, or concentrating an infectious agent. The policy should regulate material changes in phenotype, concentration, purity, and exposure potential, not only the mechanism by which the underlying genotype arose.

Category structure

Section IV-2 broadly includes genetically modified cells, viruses, and organisms, then separately lists wild-type or genetically modified RG2 biological agents for which lower containment is requested. The relationship between these clauses and Section IV-3 is unclear. NIH should explain whether this provision is intended to govern an initial request to work below standard containment, subsequent work conducted under a previously approved lower-containment determination, or both. A coherent structure would mirror the treatment of RG3 and RG4 agents: place the initial request for a novel lower-containment determination at the appropriate higher review tier, publish or otherwise catalog the resulting precedent, and permit subsequent qualifying uses through a lower institutional tier unless the agent, modification, manipulation, or facility materially differs. The final policy should eliminate redundant clauses and provide a decision tree showing how agent RG, modification status, procedure, prior NIH determinations, and requested containment interact.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft's mandatory public-posting regime is excessive and insufficiently connected to risk reduction. Current NIH policy already requires public posting of approved IBC minutes for meetings held on or after June 1, 2025, and the draft would go substantially further by mandating a template, a continuously updated public IBC roster, public incident reports, NIH responses, institutional procedures, staff-training synopses, and multi-year posting obligations. Transparency is legitimate, but disclosure should have a defined safety purpose and be calibrated against privacy, security, proprietary, personnel recruitment, and biosecurity concerns. Detailed public accounts of protocols, vulnerabilities, incidents, personnel, and deliberations may deter candid discussion and committee service without improving laboratory practice. The draft refers to "appropriate and allowable redactions" but does not provide sufficiently concrete, uniform standards, leaving institutions exposed to inconsistent disclosure decisions.

The policy should require public posting of high-level governance information and de-identified aggregate safety outcomes, while making detailed protocol records and deliberative materials available to NIH for oversight rather than automatically publishing them. At a minimum, NIH should establish explicit redaction rules; protect security-sensitive, proprietary, personnel, medical, and dual-use information; permit role-based rather than named public rosters where appropriate; and require incident summaries that emphasize causes, corrective actions, and lessons learned rather than operational details.

6. Other feedback relevant to this resource: A six-month effective date is unrealistic for a policy that applies to new and ongoing work, including non-NIH-funded research, and requires new assurances, protocol triage, committee procedures, web infrastructure, templates, training, records systems, and likely additional personnel. The final policy should provide at least 24 months after publication of all operative guidance and should use phased implementation. A reasonable sequence would be institutional governance and assurance infrastructure; prospective review of newly initiated higher-risk work; transition of active higher-risk protocols; and then migration of lower-risk and legacy protocols. NIH should also provide model forms, decision trees, standardized definitions, training modules, and a mechanism for institutions to obtain binding interpretations during implementation.

Before finalization, NIH should:
1. Reissue a substantially revised draft together with all binding templates and implementation guidance.
2. Remove slogans, including “gold-standard”, and replace them with defined, measurable policy objectives.
3. Preserve PI ownership of experiment-level risk assessment while defining proportionate IBC and NIH review roles.
4. Define material amendments and create streamlined amendment procedures for changes that remain within previously approved risk parameters.
5. Add exemptions, notification pathways, staff review, delegated review, and umbrella protocols for low-risk work.
6. Conduct an administrative-burden and federal-capacity analysis and provide implementation support.
7. Replace the six-month deadline with a phased period of at least 24 months after all guidance is final.
8. Narrow and operationalize “potential risk,” “emerging,” “novel,” “low-risk transgene,” “well-characterized cell line,” and related terms.
9. Add a technically complete framework for viral vectors, replicons, helper systems, infectious clones, and clinical gene-delivery platforms.
10. Clarify treatment of cell-free infectious or toxin-encoding nucleic acids.
11. Rework influenza provisions around phenotype and consequence rather than majority-segment arithmetic.
12. Calibrate genetically modified cell and primary cell review to credible risk.
13. Address selection and enrichment that increase hazard without necessarily introducing a new mutation.
14. Establish a coherent One Health and interagency jurisdictional framework.
15. Replace automatic detailed public disclosure with risk-informed transparency, uniform redaction rules, and de-identified safety reporting.

129. Kerri Kwist

I am responding: On behalf of myself

Name: Kerri Kwist

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: My main concern with the scope of this new policy is the lack of oversight of plant work. Although plant work does not directly affect human health, the consequences of incidents or an escape from containment could be similar in regards to effect on communities. As someone who lives in an agricultural area, this could have a negative effect on the businesses and the people who live here.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: This feedback is in regards to the Incident Reporting form as the parent of college students. My issue with this form is that the PI's name will be listed on the form that will be posted on the website. By posting the specific lab an incident occurred in, with the level of detail also required from this form, I'm concerned the medical confidentiality of students who may be involved in incidents will not be able to be protected.

6. Other feedback relevant to this resource: N/A

130. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy is extremely general and difficult to interpret. For example, Section IV-1 says that NIH will need to approve 1. Zoonotic agents that the BMBL does not give a risk group or minimum containment level. The BMBL does not have risk groups except those it references from the NIH Guidelines. Additionally, it doesn't give a containment level for many specific agents because the the majority of zoonotic agents that are known are given risk groups in the NIH Guidelines. Is the NIH prepared to review and approve all of the agents not listed in the BMBL? The BMBL is not an agent-specific resource.
2. Initial requests to lower containment for research involving wild type of genetically modified RG3 or RG4 biological agents (e.g., experiments with attenuated or replication-defective constructs). Does this refer to replication-defective lentivirus vectors that the NIH had previously stated could be safely used at BSL-2 (e.g., Biosafety Considerations for Research with Lentiviral Vectors file on NIH OSP website)? Does the NIH have the personnel in place to approve the amount of requests to work with replication-defective lentivirus vectors that will need to be submitted, reviewed, and approved immediately to not halt research?

What does GDMO stand for (I know, but some may not)? It is written throughout the policy but is not described or defined anywhere. In fact, Section IV-2 even lists gene drive modified biological agents as a separate entity from GDMO (that section says "e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs").

Section IV-2: what does "certain" vectors mean? How do we interpret which vectors are applicable? Many areas of the policy mention very general agents and materials, with no guidance on what is meant. Another example of the generalized confusion is Section IV-3 that Research conducted with transgenic organisms at BSL-1/ABSL-1 needs to be reviewed by the IBC (or a delegated review). Does this include the purchase, housing, breeding, and experiments that do not involve administration of any biological substances for every transgenic rodent line that is obtained from a vendor, even though decades of use of these rodents has shown that the majority do not have any risks associated to the humans or the environment? Most of the risks associated are related to animal care concerns (e.g., they are

immunocompromised and require specific care and containment practices to protect the animal).

Additionally, this policy is meant to modernize the current guidelines being used. Yet, "transgenic" is an older term used when transgenic animals were the only type of modification possible. That is no longer the case (e.g., site-directed, edited, etc.). Using terms like "transgenic", without a clear definition of what the policy means by that word, is another route of misinterpretation by those trying to be in compliance with the policy. "Transgenic" is one of the areas many IBCs have had dedicate to clarifing with their researchers to make sure all applicable work was reported to the IBC currently.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): What are the NIH's plans to approve all of the institutional assurances in a time frame to not stop research from being performed, and without jeopardizing the ability of researchers to maintain their funding award progress reporting deadlines? The draft policy says that no research can be performed that is applicable to the policy until the assurance is approved by the NIH, once the policy is finalized. How is this feasible, when the institutions do not even have a template or information for submitting the assurances before the policy is finalized. This is again another forced non-compliance. One moment the institutions will be in compliance with the NIH Guidelines, and then suddenly they will be out of compliance with the new NIH policy because the NIH OSP does not have the resources to approve all of the assurances in a timely fashion (this is based on concerns related to the current timelines provided by our IBC for NIH OSP approving IBC roster updates).

3. Continued utility of Risk Groups: Removing risk groups as part of a risk assessment is irresponsible. The required containment practices and the risks associated with specific organisms are different things. To clump everything as a biosafety level goes against the goal of strengthening oversight of biosafety. It is easy enough to include a step in the risk group analysis to include assessment for genetic modifications. It would be similar to how organisms proven to be attenuated (e.g., FDA-approved vaccine strains) have already been given a lower risk group whereas those not validated yet maintain the same risk group as the wild type. As long as clear reasoning is applied to the risk group designation method, there is no reason that it is not applicable to all organisms and modifications. It is an easy tool for even students to use- what happens if I am exposed to this organism, are there potential treatments, and "this is why they are making me follow these requirements when using it". The BSL does not tell you anything about why you need to use the practices being required and what can happen if you are exposed.
The BSL is part of the mitigation plan after knowing the risks of the organisms and procedures; not the assessment itself.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Requiring minutes to be posted "immediately" after approval is not a responsible term to use in a policy. If a deadline is being given it needs to be a realistic and feasible time-frame. "Immediately" does not take into account what is required to post items on a website (most institutions do not allow people within a department to just upload items. There are procedures to follow), and what happens when a person in the IBC or the website side is out of the office? Without taking realistic abilities into account for this type of request, a requirement of "immediately" is a forced non-compliance at some point in time for every institution. And not posting the minutes immediately in no way affects the actual safety and oversight of the

research; it only affects the timeliness of human curiosity for a meeting that happened in the past, which should not be the priority of a biohazard policy. Transparency is important, but not at the expense of institutions not providing appropriate time and resources to actually making sure the researchers are maintaining biosafety and biosecurity compliance in an attempt to reach an unattainable goal of posting items online.

When the instructions for posting things online has unattainable timelines, and is more structured and is better clarified, than the information in the policy for mitigating the risks associated with the research itself, there is a problem. The policy seems to have been written with honest concerns raised but without addressing how the risks should be mitigated. And so those applicable to the policy are left with no choice but to have widely different interpretations of what is being said in the policy, what they are being asked to do, and how they are supposed to be in compliance. The NIH Guidelines had initially been written by scientists who were listening to the concerns of others about the research being done, and so it was written to be understood by those performing tasks applicable to it. The new draft policy is essentially a list of concerns about research with biohazardous agents that need to be addressed, but gives no clear guidance on how to do so.

6. Other feedback relevant to this resource: N/A

131. Janelle Gagnon

I am responding: On behalf of myself

Name: Janelle Gagnon

Name of Organization: Mount Holyoke College

Type of Organization: Academic Institution

Role: Other

Role - Other: Laboratory Director

Date Submitted: 10/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Under the proposed requirements, I have concerns that the reporting policy is too broad and does not distinguish between routine, low-risk incidents and events that pose a serious biosafety concern. While transparency and accountability are essential, requiring public disclosure of every incident, including minor scratches or injuries that require only routine first aid, may be disproportionate to the actual risk. I worry about the implications it may have for the institution being broadcasted on a public-facing page. Specifically, if every minor incident must be reported it might discourage faculty PIs from training undergraduates within their laboratories.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

132. University of Wisconsin–Madison

I am responding: On behalf of an organization

Name: Dorota Grejner-Brzezinska

Name of Organization: University of Wisconsin–Madison

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/9/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: An effective biosafety and biosecurity policy is risk-based, technology-agnostic, and written to allow flexibility for local implementation. By empowering IBCs to set requirements based on risk assessment and removing most of the prescriptive language, the draft NIH Policy largely succeeds in achieving this.

One of the stated goals of the NIH Biosafety Modernization Initiative is to remove red tape for low-risk research. However, the expanded and unclear scope of the draft policy, in addition to new requirements under the policy, will increase the administrative burden for our IBC, Biosafety Program, and PIs. Areas where there is a lack of clarity or an increase in administrative burden are called out in comments for specific sections below.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Section IV. Categories of Oversight for Research Based on Risk
• Overall, we agree with the categorization of research into the three categories described.
o We appreciate that the categories are defined by the level of risk, and that only higher risk research requires review and approval from NIH.
• Some agents are not mentioned in this categorization and should be explicitly added to avoid confusion.
o We recommend the following be added to “Requires IBC Review and Approval Before Initiation”:
o Genetically modified RG3 and RG4 biological agents when lowering of containment is not requested
o The addition of an antibiotic or antiviral resistance trait to a pathogen that would negatively impact treatment of infection by that pathogen in humans
o We recommend the following be added to “Requires Review and Approval Before Initiation and May Be Delegated”:
o Genetically modified RG2 biological agents when lowering containment is not requested
Section IV-1. Research That Requires NIH and IBC Approval Before Initiation
• Overall, we agree that only the highest risk research should require NIH approval.
o Similar to above, the sentence “Research involving … agents for which the RG classification or a

recommendation for minimum containment level is not available in the BMBL" is confusing. BMBL does not contain risk group information. As stated above, we recommend that this be clarified and that multiple sources be allowed for determining risk group, such as the Americal Biological Safety Association Risk Group Database, Government of Canada Pathogen Safety Data Sheets, and a searchable list or database to be created and maintained by NIH.
o We recommend that established replication incompetent HIV-based lentiviral vector systems be explicitly excluded from requiring NIH approval for lowering containment of genetically modified RG3 agents. Alternatively, these should be included in the published list of approved determinations for lower containment when the policy goes live.

Section IV-2. Research That Requires IBC Review and Approval Before Initiation
• Clarifications are needed to properly categorize research in this category.
o The bullet "Research involving genetically modified cells, viruses, or organisms other than plants" seems to overlap with bullets under Section IV-3. Does this include all genetically modified cells? Viral vectors? Transgenic rodents? What is meant by "certain vectors"? Subsets of these that fall under delegated review should be explicitly excluded here.
o As stated above, it is not clear whether the intent is for the policy to cover all GDMOs, or only those that pose a risk or potential risk to human health (e.g., vectors of human disease). Plants are excluded elsewhere, but would gene drive modified plants be in scope?
o What is meant by "gene drive modified biological agents"? How does this differ from GDMOs?
o The wording of the bullet "Research involving toxins listed as Select Agents" does not align with definitions under the Select Agent Regulations. Toxins are not "select agents" they are "select toxins".
• Primary cells that may be contaminated by adventitious agents should be removed or limited.
o It is impossible to rule out the possibility of adventitious agents in primary cells, even with extensive testing, making this bullet unnecessarily broad.
o Primary human cells that pose a risk solely due to the potential for bloodborne pathogens are already covered by the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030.
o Primary animal cells not known or suspected of carrying zoonotic pathogens should be out of scope of the policy and not require IBC review.
o If kept, we recommend revising this to "Research with primary cells that are known or may be reasonably suspected to be contaminated with human or zoonotic pathogens not covered by the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030" and moving this to the delegated review category.
• We agree with the inclusion of clinical research but recommend revisions to the wording for greater clarity.
o We appreciate the exclusion of FDA regulated expanded access from the policy.
o "Products" is vague and should be amended to specify biological products that pose a known or potential risk to human health, such as microbes, viral vector systems, or biological toxins. As written, this could be interpreted to include chemical or radiological agents (which are outside the purview of the IBC) or biologically derived materials that pose little to no exposure risk (e.g., plasmids, antibodies).
o The inclusion of shedding as a criterium for IBC review may be problematic, as shedding data is not always available. Integration data may also not be available. We recommend adding "or for which the potential for shedding, replicating, or integrating is unknown".

Section IV-3. Research That Requires Review and Approval Before Initiation and May Be Delegated to an

Individual or Subgroup of IBC Members
• Overall, we agree that lower risk work should not require review and approval from the entire IBC prior to initiation.
o New low-risk experiments and minor amendments to previously approved research currently must wait for the next convened IBC meeting, which can cause delays to research. Delegated review will reduce wait times.
o Delegated review will also lighten busy IBC meeting dockets, freeing up more in-meeting time for discussion.
• The lowest risk research should be excluded or limited to reduce unnecessary administrative burden.
o The creation of a delegated review category does not reduce administrative burden. PIs still need to create submissions, and submissions still need to be processed and tracked.
o With the expansion of the policy to include wild type agents, toxins, and prions, the number of required submissions will increase.
o As written, the draft policy could be interpreted such that many agents previously exempt under the NIH Guidelines (e.g., RG1 E.coli and S. cerevisiae host vector systems and many transgenic rodents) now require delegated review. This creates an administrative burden with no added safety.
o The inclusion of transgenic organisms at BSL-1/ABSL-1 should be limited to those that pose a known or potential risk to human health. Under the current NIH Guidelines, many transgenic rodents purchased and bred at BSL-1/ABSL-1 are exempt from IBC registration requirements. Removing this exemption will significantly increase the number of registrations that the institution must process, review, and track. This adds significant burden to both PIs and IBCs with no added safety.
o We recommend explicitly excluding research involving genetically modified common animal models that pose little to no risk to human health, such as laboratory-bred rodents, fish, frogs, fruit flies, and non-parasitic nematodes at BSL-1/ABSL-1.
o Since RG1 organisms by definition do not cause disease in humans, “research with genetically modified RG1 biological agents” should be refined to “research with genetically modified RG1 biological agents that have been modified such that they pose a risk to human health (e.g., expression of a toxin or prion)”.
• Clarifications are needed to properly categorize research in this category.
o It is unclear what is considered a “minor amendment”. We recommend more explicit wording such as “amendments to previously approved research where there is no increase in risk”.
o Integration of viral vectors may depend on viral load. Is there a defined cutoff for what is considered “integrating”?
o As mentioned above, the terms “low risk transgenes” and “well-characterized cell lines” are not defined.
o As mentioned above, “biological toxin proteins not on the Select Agent list” should be revised to “biological toxins not listed in 42 C.F.R. Part 73 as Select Toxins” as not all toxins are proteins and none are technically “select agents” but rather “select toxins”.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): We have no comments on this section.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The University of Wisconsin-Madison thanks the NIH for providing us with an opportunity to comment on the Draft NIH

Incident Reporting Template. We are writing on behalf of the University to provide our feedback on the template.

We appreciate that the NIH has created templates in an effort to help institutions comply with the new Biosafety Policy. One of the stated goals of the NIH Biosafety Modernization Initiative is to reduce the administrative burden of biosafety programs to allow resources to be effectively allocated. However, in its current form, the draft template for incident reporting will increase administrative burden and create personal and institutional vulnerabilities.

Specifically:
• Posting all incident reports on a public-facing website will disincentivize reporting.
o Effective incident reporting must be non-punitive. Publicizing incidents will deter reporting and allow unsafe conditions or practices to persist.
o Even if redacted, incident reports often contain enough information to identify individuals that were involved, particularly in small laboratories.
o We recommend replacing the requirement to post all incident reports on a public-facing website with a requirement to publish aggregated and anonymized incident data.
• Posting all incident reports on a public-facing website creates an administrative burden.
o Due to their volume, institutions with robust research programs may have a higher number of incidents and thus many incident reports. Reviewing, redacting, and posting these on a public-facing website will require significant additional time and effort from already over-burdened safety and compliance programs without a commensurate benefit to the public. Publishing aggregated and anonymized incident data would reduce this burden while also providing transparent and timely public information.
• The mandatory template contains information that will endanger individual privacy protections.
o Good-faith reporting of incidents should not result in retaliation or adverse employment consequences. Best practice dictates that identifiable worker information should be limited to individuals with a legitimate need to know.
o The inclusion of position titles could lead to identification of individuals involved in incidents. Institutions should have the flexibility to describe individuals more generically (e.g., “employee” or “researcher”).
o IBC members, BSOs, and other biosafety professionals typically do not and should not have access to private medical records. Medical treatment and recommendations for medical treatment should remain private between an individual and their medical provider. This is particularly true when treatment information could reveal details about an individual’s personal health status. Including this information in the investigation and subsequent report violates this privacy.
• Grant information should not be required for incident reporting.
o It is not always immediately evident what grant(s) covers research involved in a specific incident.
o Having to investigate and determine the grant(s) or application(s) connected to the research is an increased administrative burden at odds with NIH’s objectives of reduced red tape and prompt reporting.
o Inclusion of grant information in incident reports will deter reporting. To be effective, incident reporting must be non-punitive. Connecting incidents to specific grants gives the perception that funding will be jeopardized by reporting. This creates a safety culture where unsafe conditions and practices go unaddressed, causing greater harm.

• The use of a mandatory template for initial notification of incidents to the NIH is unduly burdensome.
o There is often very little information available when incidents are initially reported to the IBC, Biosafety Office, or Research Office. Forcing the use of a form that may be largely blank wastes time and creates unnecessary paperwork.
o We recommend that institutions be given the option to send an email for initial notification of incidents to the NIH as is currently allowed. This path already provides an efficient mechanism for immediate reporting.
• The template could be improved by making it more concise.
o As mentioned above, we recommend removing fields related to funding information: NIH grant or contract number, NIH funding institute or center, NIH program officer name and email address.
o We recommend removing the field for reporting to other agencies. There is no clear purpose for including this information.

UW-Madison is committed to protecting our personnel and community and we are proud of our robust safety programs. We ask that the NIH allow greater flexibility for how institutions handle incident reporting to reduce the ever-growing administrative burden of research compliance and make local judgements to protect their personnel.

The University of Wisconsin-Madison thanks the NIH for providing us with an opportunity to comment on the draft NIH template for Institutional Biosafety Committee (IBC) meeting minutes. We are writing on behalf of the University to provide our feedback on the template.

We appreciate that the NIH has undertaken efforts to create templates to help institutions comply with the new Biosafety Policy. One of the stated goals of the NIH Biosafety Modernization Initiative is to reduce the administrative burden of biosafety programs to allow resources to be effectively allocated. However, in current form, the draft template for IBC meeting minutes will increase administrative burden and create vulnerabilities for US research.

Specifically:
• The use of a mandatory template will in many cases increase the amount of effort needed to generate IBC meeting minutes.
o Many IBCs use software to manage their meetings, including generation of minutes. For example, at UW-Madison our online software will automatically generate IBC meeting minutes based on information entered when the motions are recorded. Having to use a mandatory template will require us to either do extensive reprogramming of the software (which may not be possible) or create IBC meeting minutes manually instead.
o Manually generating IBC meeting minutes will be especially burdensome for institutions with large research portfolios. For example, in the last five years the UW-Madison IBC has reviewed an average of 326 registrations per year. With the expanded scope of the new NIH Biosafety Policy, this will only increase.
• The mandatory template includes too much detail.
o We appreciate the NIH's acknowledgement that redaction of minutes is appropriate to protect private or proprietary information, including, for example, information that would compromise institutional or

national security.
o While we applaud the NIH's drive for transparency, the level of scientific detail asked to be included in the minutes is not accessible to the majority of the public. To demonstrate to the public that the IBC is fulfilling its responsibilities, the information in the minutes should be accessible to a non-scientific audience. Descriptions should be less technical and more descriptive.
o We recommend the examples for the "Project Overview" and "Risk Assessment and Discussion" in the template be revised. For example, "The amendment proposes to add experiments using a replication-incompetent viral vector to express non-oncogenic, non-toxic proteins in established human cell lines at BSL2" captures the type of work and level of risk with less scientific and experimental detail.
• The template could be improved by making it more concise and reorganizing some sections for greater clarity.
o The section on "Quorum" is superfluous since the minutes list the IBC members present and no meeting business can occur without quorum.
o "Review of Prior Business" and "New Business/Additional Topics" could be combined into a single section for "Other Business".
o The line where "New IBC Registrations and Amendments for Review (repeat for each registration)" ends is unclear.
o The section "Readout of Any Projects Approved by Delegated Review" is embedded in the middle of the "New IBC Registrations and Amendments for Review (repeat for each registration)" sections, which is confusing. We recommend moving this section to before or after the new registrations and amendment for review.
o "Occupational Health Representative Review (if applicable)" can be incorporated into the "Risk Assessment and Discussion" section.

As a public institution, UW-Madison is committed to documenting the exceptional work that our IBC does to review and oversee research for the NIH and the public. We ask that the NIH allow greater flexibility for how institutions may fulfill documentation requirements to reduce the ever-growing administrative burden of research compliance and make local judgements to protect their personnel.

Thank you for your consideration.

6. Other feedback relevant to this resource: General Definitions
• There are several important definitions that are missing and should be added. These include the following:
o Risk groups
o Biosafety level
o GDMO
o Incident
o Exposure and potential exposure
o Release
o Adventitious agent
o Low risk transgene
o Well-characterized cell line
o Higher risk manipulation

o Enhanced containment
• In addition, several definitions are vague or ambiguous and should be clarified.
o The overall use of “agent” in definitions and throughout the policy is unclear (e.g., emerging agent, novel agent). Does this refer to microbes, other organisms, parts and pieces of microbes or organisms?
o The definition of “biological agent” will be confusing for scientists that use this term more generally. We recommend replacing this term with “biohazardous agent” for greater clarity. If the term “biological agent” is kept, we recommend adopting the definition from 18 USC 178 for better alignment across federal agencies.
o “Emerging agent or organism” should specify that it is biological in nature and is known to or can be reasonably expected to pose a potential risk to human health.
o “Novel agent or organism” should specify that it is biological in nature and is known to or can be reasonably expected to pose a potential risk to human health.
o We recommend removing “or animals” from the definition of “prions and self-aggregating proteins” since animal health is outside the scope of the policy.
o “Toxin” is defined as a protein or peptide, but not all biological toxins are proteins.
o The phrase “causes harm to humans” in the definition of “toxin” is unclear and could be interpreted to include many proteins that are not typically considered biological toxins. We recommend revising this definition to include a minimum LD50 and adopting the definition from 18 USC 178 for better alignment across federal agencies.
o The definition of “zoonotic” should specify that it refers to agents that are biological in nature.

Description: Combined response on Biosafety policy, IBC minutes, and incident reporting template

133. Lauren Danridge

I am responding: On behalf of myself

Name: Lauren Danridge

Name of Organization: Not applicable

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/10/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of the proposed policy is insufficiently defined and contains significant ambiguities that must be resolved before implementation. The current language creates substantial risk of inconsistent interpretation among institutions and will result in uneven oversight across the research enterprise. The policy defines covered research as that involving a "known or potential risk to human health," yet fails to establish any objective threshold for what constitutes a potential risk. As written, virtually any biological material could be interpreted as falling within scope, rendering the definition overly broad and operationally unworkable. NIH must provide clear criteria for determining when a biological material or activity is subject to oversight.

The policy also relies on numerous undefined terms that directly affect scope and applicability. Terms including "organism," "emerging biological agent," "emerging technologies," and "manipulations" must be explicitly defined. Failure to define these terms will inevitably result in inconsistent institutional interpretations and unequal regulatory treatment of similar activities.

The scope statement is internally inconsistent. The policy is ostensibly focused on risks to human health, yet numerous provisions require assessment of environmental impacts and ecological risks, including mandated expertise in environmental risk assessment and representation of community interests related to environmental protection on the IBC. NIH must either explicitly incorporate environmental risks into the stated scope of the policy or remove requirements that extend beyond the stated purpose of protecting human health.

The policy further fails to clearly articulate the treatment of several research categories that commonly require institutional review, including research involving human-derived materials, stem cells, established cell lines, attenuated organisms, nonreplicating vectors, and biological materials that may present indirect or conditional risks. NIH must provide explicit guidance, exclusions, and examples to prevent institutions from unnecessarily expanding oversight of low-risk activities.

Additionally, the policy's treatment of toxins, prions, self-aggregating proteins, and zoonotic agents is not fully reconciled with the definition of biological agents. NIH must clarify how these materials fit within the overall biohazard framework and establish a consistent regulatory approach across all categories of covered materials.

Finally, the policy does not adequately address risks arising from the use of biological agents in animal research. NIH must clarify whether secondary exposures, shedding, transmission, animal-associated risks, and occupational hazards associated with animal studies fall within the intended scope of oversight. This gap is particularly significant given the widespread use of animal models in biomedical research.

Additional specifics:
The phrase "known or potential risk to human health" is overly broad and lacks objective criteria. NIH should establish a threshold for oversight or provide examples of activities that are outside the policy's scope. As written, the definition could encompass virtually all work involving human-derived materials, cell culture, or microorganisms

The policy repeatedly references environmental protection and ecological risk assessment, yet the scope is described as human-health focused NIH must either revise the scope to explicitly include environmental risks or remove requirements that extend beyond a human-health framework. The policy currently contains a fundamental inconsistency regarding the risks it intends to regulate.

NIH should explicitly state whether human stem cells, induced pluripotent stem cells, primary human tissues, and established cell lines are intended to fall within the scope of this policy when they are not genetically modified and do not contain infectious materials.

NIH should clarify the boundaries between laboratory research, clinical research, and environmental release activities to ensure consistent application of oversight requirements.

The policy does not adequately address secondary risks arising from animal research, including shedding, transmission, environmental contamination, escape, occupational exposure, and risks occurring after administration of biological agents to animals. NIH should expressly address these scenarios within the scope and risk-assessment framework.

Please define:
• Potential risk to human health
• Organism
• Emerging biological agent / Emerging agent
• Emerging technologies
• Manipulations
• Product
• Clinical product
• IBC Delegate

• Significant risk to human health
• Records related to awards

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed tiered oversight framework lacks sufficient clarity regarding the division of authority between NIH and institutional biosafety programs. As drafted, the policy creates uncertainty regarding whether NIH intends to establish general oversight expectations or exercise direct regulatory authority over specific research activities. This ambiguity must be eliminated before implementation.

The policy repeatedly requires institutions to obtain NIH authorization or determination before proceeding with certain categories of research involving emerging, novel, or zoonotic agents. However, NIH provides no description of how such reviews will occur, what standards will be applied, which NIH office will make decisions, or how long institutions should expect to wait for a response. A regulatory requirement that lacks defined procedures and timelines is unacceptable and creates significant operational uncertainty for institutions and investigators. NIH must establish transparent review pathways and enforceable review timelines prior to implementing these requirements.

The policy appropriately recognizes the role of Institutional Biosafety Committees but does not sufficiently acknowledge that IBCs possess direct knowledge of local facilities, personnel qualifications, operational practices, and institutional risk management systems. NIH should not unnecessarily centralize decisions that can be effectively evaluated at the institutional level by qualified experts. Federal oversight should be reserved for truly novel, unprecedented, or exceptionally high-risk research activities. Routine risk assessment and containment determinations should remain the responsibility of institutions.

The proposed framework will also create unnecessary duplication unless NIH commits to publicly posting biosafety determinations involving emerging, novel, and zoonotic agents. Institutions should not be required to repeatedly submit substantially similar requests for NIH review when prior precedential determinations already exist. NIH must establish and maintain a publicly accessible repository of containment decisions, interpretations, and policy determinations to promote consistency and transparency throughout the research community.

Most importantly, the final policy must maintain a strict relationship between risk and oversight burden. The expansion of policy scope cannot be allowed to result in low-risk activities being subjected to the same level of review and administrative requirements as higher-risk research. Such an outcome would divert limited institutional resources away from activities that present meaningful biosafety concerns. The final policy must preserve streamlined review mechanisms, delegated review authorities, administrative determinations, and clearly defined exclusions for low-risk activities. Oversight resources should be directed where they provide measurable biosafety benefit rather than applied uniformly across all covered research.

In its current form, the tiered oversight framework does not provide sufficient clarity regarding responsibilities, authority, timelines, or mechanisms for federal decision-making. These deficiencies should be corrected before the policy is finalized.

Additional specifics:
The policy repeatedly states that institutions must obtain NIH authorization before conducting certain activities involving novel, emerging, or zoonotic agents.

Which NIH office?
Review criteria?
Appeal process?
Required submission contents?
Timelines?

NIH should not impose a mandatory approval process without publishing review criteria, procedural requirements, decision authorities, and response timelines. Such information is necessary for institutions to effectively plan and conduct research activities.

NIH should establish target review timelines for all federally required determinations. Delayed decisions can significantly affect grant start dates, staffing, facility scheduling, and research progress.

NIH should publish all containment determinations, precedent-setting interpretations, approvals of containment reductions, and determinations involving emerging or novel agents. Institutions should not be required to repeatedly seek NIH review for issues that have already been evaluated and resolved.

The proposal appears to shift decision-making authority toward NIH while relying on institutions to perform the underlying risk assessments, monitoring, inspections, training, incident investigations, and compliance activities. NIH should clearly justify when federal review adds value beyond local expert review.

3. Continued utility of Risk Groups: Risk Groups (RGs) should be retained as the primary framework for hazard communication and initial agent characterization. RGs provide a widely understood, objective, and standardized method for communicating the potential hazards associated with biological agents and promote consistency across institutions. However, RG classification alone should not dictate containment requirements or determine the level of oversight. As has long been recognized, appropriate biosafety determinations require consideration of the specific characteristics of the agent, the nature of the proposed work, the procedures being performed, scale of use, routes of exposure, personnel expertise, available facilities, and other risk-mitigation measures.

The final policy should preserve institutional authority to conduct experiment-specific and site-specific risk assessments rather than replacing existing practices with prescriptive federal requirements. Institutional Biosafety Committees are best positioned to evaluate local facilities, personnel qualifications, operational practices, occupational health programs, and available containment capabilities. The policy should support, rather than diminish, this longstanding role.

The proposed definition of genetic modification warrants further refinement. As drafted, the definition includes changes resulting from passaging, reassortment, and chemical or radiological means in addition to deliberate genetic engineering. This approach could inadvertently subject conventional selection, adaptation, mutagenesis, strain improvement, and other routine laboratory activities to increased

oversight even when such activities do not result in increased biosafety risk. Oversight should be based on the characteristics and risk profile of the resulting agent rather than the method used to generate the change.

NIH should clearly distinguish deliberate genetic engineering from naturally occurring adaptation, laboratory selection, reassortment, passaging, and induced mutagenesis. Not all genetic changes create meaningful biosafety concerns, and oversight requirements should remain proportional to demonstrated risk rather than being triggered solely by the occurrence of genetic alteration.

The policy should also avoid rigid containment requirements that may conflict with established risk-assessment practices. For example, a universal minimum containment requirement for genetically modified organisms may not align with specialized systems used for arthropod research, aquatic organisms, greenhouse studies, ecological research, or other nontraditional research settings. Institutions should be permitted to utilize equivalent containment approaches when they provide comparable protection and are supported by appropriate risk assessment. NIH should develop technology-specific guidance where necessary rather than relying on broadly applicable containment mandates.

Similarly, provisions addressing influenza viruses should provide clear and objective criteria regarding when enhanced containment is warranted. Containment requirements should be based on demonstrated phenotypic characteristics and risk-relevant attributes rather than broad language that could encompass a wide range of constructs without regard to actual biosafety implications.

In summary, RGs remain an effective starting point for hazard classification and should continue to serve that function. The final policy should preserve institution-led, risk-based decision making; distinguish genetic engineering from other forms of biological change; and avoid prescriptive containment requirements that are not calibrated to the characteristics and risks of the specific research being conducted. This approach will promote both consistency and flexibility without creating unnecessary oversight burdens.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary compliance should be supported through access to publicly available guidance and national determinations rather than through additional oversight structures or administrative requirements. Institutions should be able to rely on published NIH containment determinations, risk classifications, guidance documents, and implementation resources rather than repeatedly requesting the same information. NIH should maintain a searchable database of determinations involving emerging, novel, and zoonotic agents and allow institutions to rely on published precedents where appropriate. The policy should also support flexible implementation models. Voluntary compliance should not result in additional reporting, approval, registration, certification, or assurance requirements that create administrative burden without corresponding biosafety benefit.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Comments on Draft Incident Reporting and Draft Meeting Minutes Templates

The draft incident reporting and meeting minutes templates impose substantial administrative burdens that are not justified by a corresponding improvement in biosafety oversight, risk management, or public safety. The proposed requirements significantly expand institutional documentation, review, and public disclosure obligations while providing little evidence that the additional processes will improve biosafety outcomes.

Meeting Minutes Template

The fundamental issue is that the minutes template appears to shift IBC minutes from documenting committee actions and decisions to documenting the underlying scientific review itself. That creates substantial administrative burden while providing little additional biosafety value. The quality of an IBC review should be judged by the appropriateness of its decisions and risk-management strategies, not by the length of its meeting minutes or incident reports.

The Template Converts Minutes into a Secondary Protocol Record. The proposed template transforms meeting minutes into a secondary protocol document by requiring extensive duplication of information already maintained within protocol submissions, risk assessments, training records, and institutional systems. This creates substantial administrative burden without improving the quality of biosafety review or oversight outcomes.

No Demonstrated Connection Between More Detailed Minutes and Better Biosafety. NIH has not demonstrated how increasingly detailed meeting minutes improve biosafety outcomes, incident prevention, containment practices, or regulatory compliance. Documentation should support committee decision-making and record institutional actions rather than serve as a duplicate scientific review record.

Requirement to Document Routine Business Creates Scope Creep. The accumulation of documentation expectations for routine operational activities substantially expands administrative workload while providing limited additional oversight value. The purpose of minutes should be to document committee actions and determinations rather than serve as a comprehensive institutional biosafety record.

Public Posting Creates Incentive to Over-Document and Then Over-Redact. The more information institutions are required to include in public-facing meeting minutes, the greater the burden associated with review, redaction, legal assessment, and public posting. Expanding minute content creates additional administrative work without strengthening biosafety oversight.

Incident Reporting Template

The most significant concern is the expansion of oversight and documentation requirements for incidents that do not warrant NIH reporting. The proposed policy requires institutions to investigate, document, review through the IBC, and publicly post information regarding incidents that NIH itself has determined are not significant enough to require federal notification.

This creates a new category of institutionally reportable and publicly disclosed events without demonstrating how such requirements improve biosafety. Requiring formal IBC review and public

posting of minor incidents, animal bites and scratches, routine first-aid events, and other low-risk occurrences represents regulatory creep that will consume institutional resources that would be better directed toward meaningful risk reduction activities.

Minor Incidents Are the Biggest Burden Issue. Requiring formal documentation and public posting of discussions regarding minor incidents that are not reportable to NIH represents a significant expansion of administrative obligations. Institutional resources should remain focused on significant biosafety events rather than generating public records for incidents that pose minimal risk and do not warrant federal notification.

Oversight should remain proportional to risk. Events that do not meet NIH reporting thresholds should generally remain subject to local management and corrective action processes unless there is a clear justification for additional review.

Particularly concerning is the use of the term"significant" without measurable criteria. Institutions cannot be expected to apply a consistent standard when the policy does not establish one. The inevitable result will be variability in reporting practices, inconsistent national data, and overreporting driven by institutional concern about regulatory scrutiny.

The proposal appears to assume that greater transparency is achieved simply by publishing more information. However, NIH has not demonstrated how public posting of minor incidents or extensive committee discussions improves biosafety performance, accident prevention, or public protection.

Recommendations

NIH should revise the templates to:

Focus reporting on significant biosafety events.
Establish objective reporting thresholds and definitions.
Eliminate public-posting requirements for non-NIH-reportable incidents.
Limit meeting minutes to committee actions, determinations, and votes rather than detailed scientific review narratives.
Avoid duplicative documentation requirements for information already maintained elsewhere in institutional oversight systems.

As currently drafted, the templates substantially increase administrative burden, expand oversight into low-risk institutional matters, and create new public disclosure obligations without demonstrating a meaningful improvement in biosafety outcomes.

6. Other feedback relevant to this resource: The success or failure of the proposed policy will depend less on the regulatory text itself and more on the quality, completeness, and usability of the implementation resources. These resources should focus on clarifying policy expectations, reducing ambiguity of the fundamental terms (e.g., significant, biological agent), while preserving institutional flexibility to develop oversight practices that are appropriate for their research activities, organizational structures, available expertise, facilities, and risk profiles.

Implementation resources should not create additional approval pathways, reporting requirements, prescriptive operational procedures, or de facto regulatory requirements beyond those expressly contained within the policy

NIH Must Clarify the Process for Novel, Emerging, and Zoonotic Agents: The policy requires institutions to seek NIH determinations for certain categories of agents but provides little operational guidance regarding how this process will function. If NIH intends to maintain a role in such determinations, NIH should clearly publish:

-Submission requirements
-Required supporting documentation
-Review criteria
-Risk factors considered during review
-Expected review timelines
-Processes for obtaining clarification

Institutions cannot effectively comply with requirements when the underlying review process is undefined.

NIH Must Publish Determinations and Policy Interpretations and maintain a publicly accessible repository. Institutions should not be required to submit repetitive requests regarding issues NIH has already evaluated. Publication of precedent-setting determinations would improve consistency across institutions while reducing administrative burden for both institutions, PIs, and NIH

134. Mass General Brigham

I am responding: On behalf of an organization

Name:

Name of Organization: Mass General Brigham

Type of Organization: Healthcare Institution

Role: Organizational Official

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: MGB-Comments-on-NIH-RFI-Biosafety.pdf

Mass General Brigham

Lyric Jorgenson, PhD
Associate Director
Office of Science Policy
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

October 13, 2026

Submitted via https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

Dear Associate Director Jorgensen:

Mass General Brigham appreciates the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112). Mass General Brigham is a not-for-profit academic health care system committed to patient care, biomedical research, education, and service to the community. The system includes two academic medical centers, Massachusetts General Hospital and Brigham and Women's Hospital, and specialty hospitals that include McLean Hospital, Mass Eye and Ear, and Spaulding Rehabilitation Hospital. The Mass General Brigham Institutional Biosafety Committee (IBC) provides centralized biosafety review and oversight for biological research conducted at these institutions. Mass General Brigham and its affiliated institutions receive NIH funding and conduct a substantial and diverse portfolio of basic, translational, animal, and clinical research subject to federal, state, local, and institutional biosafety requirements.

Mass General Brigham supports NIH's objective of establishing a contemporary, risk-based framework that promotes safe, responsible, secure, and accountable biomedical research. However, several proposed requirements would create substantial administrative burdens, introduce uncertainty, or potentially discourage transparent incident reporting without producing a corresponding improvement in biosafety.

Recommendations to Improve Reporting of incident reports

As currently drafted, Mass General Brigham has concerns about the proposed requirement to publish individual biosafety incident reports. The policy requires institutions to post all incident reports on a public-facing institutional website using the required NIH template. This includes both significant incidents reported to NIH and lower-risk incidents reviewed only by the IBC, such as certain animal bites, scratches, escapes, improper dispositions, and incidents at BSL-1/ABSL-1 or BSL-2/ABSL-2 for which only first aid is administered.

The public-posting requirement is materially different from public access to IBC meeting minutes. Incident reports contain concentrated information about a specific event, including the

individual(s), laboratory, and research activities involved. The required NIH template calls for an incident narrative, information about the biological material, investigation findings, root-cause analysis, and corrective actions. It also instructs institutions to write reports in lay language to promote public transparency.

Although the template prohibits personally identifiable information about individuals, it expressly requires the principal investigator's name to remain in the public report. Redaction is limited to proprietary or private information, confidential commercial information, and information whose disclosure would directly compromise institutional or national security.

These protections may be insufficient to prevent identification of affected personnel. In a small laboratory, specialized research program, or department with a limited number of employees, the combination of the principal investigator's name, biological agent or research material, incident type, general setting, personnel position, circumstances of the event, medical response, root cause, and corrective actions may allow colleagues or members of the research community to identify an affected individual even when the individual's name is removed.

Public posting may also discourage prompt reporting of minor incidents, suspected exposures, and near misses. Mass General Brigham requires personnel to report potential or overt exposures, suspected laboratory-acquired infections, and possible violations even when the individual does not seek evaluation from Occupational Health or an emergency department. Effective biosafety oversight depends on personnel reporting these matters promptly and candidly. The requirement to publish an individual report may create a perceived adverse consequence for reporting and may therefore weaken the reporting culture the policy is intended to strengthen.

Publication of institution-only incidents is particularly concerning. NIH has determined that these lower-risk incidents do not require federal reporting, yet the draft would require institutions to prepare and publish individual reports about them. The transparency benefit of publishing an animal scratch, minor first-aid event, or other lower-risk incident is unclear, while the potential effects on employee privacy, reporting behavior, institutional workload, and public interpretation are substantial.

NIH's proposed National Biosafety Data and Safety Analysis Center provides a more appropriate mechanism for public learning from biosafety incidents. Aggregated and de-identified analysis can identify recurring hazards, contributing factors, corrective actions, and national trends without exposing individual employees, laboratories, or institutions through event-specific public reports.

Mass General Brigham recommends the NIH:

- Remove the requirement that institutions publicly post individual incident reports.
- Require institutions to report applicable incidents to NIH and maintain appropriate institutional records without making each report public.

- Use the National Biosafety Data and Safety Analysis Center and NIH's annual incident summary to publish aggregated, de-identified information about national trends, recurring causes, and effective corrective actions.
- Exclude incidents requiring only institutional or IBC review from any public-posting requirement.
- If public posting is retained, limit it to a standardized public summary of a confirmed significant incident that was reportable to NIH.
- Do not require the public summary to identify the Principal Investigator, laboratory, department, affected personnel's position titles, specific location, distinctive agent or construct, medical response, or other details that could reasonably permit identification.
- Permit institutions to redact combinations of otherwise nonidentifying information when the combined information could reasonably identify an affected person, laboratory, or research program.
- Permit institutions to delay publication until the investigation, occupational health evaluation, corrective actions, legal review, and applicable employment processes are complete.
- Evaluate whether mandatory public disclosure could discourage reporting of minor incidents and near misses before imposing this requirement.

USE A RISK-BASED RENEWAL FRAMEWORK

The draft policy provides that IBC approval may not exceed three years, after which the investigator must submit a de novo registration for review. It does not explain the scientific or risk-based rationale for selecting a three-year interval or require the renewal pathway to account for whether the research, biological materials, procedures, containment, or applicable biosafety standards have changed.

Mass General Brigham has effectively used a five-year approval cycle for over 15 years. During each approval period, the principal investigator must review the registration annually to confirm that it accurately describes the research. Changes must be submitted prospectively through the amendment process, and scientific changes that may affect the biosafety assessment, receive BSO review and, when necessary, review by the convened IBC. The IBC may also shorten the approval period when warranted.

This combination of annual investigator review, prospective amendment review, and periodic comprehensive renewal provides continuing oversight throughout the approval period. The registration does not remain unchanged and unexamined for five years. Material changes in biological agents, recombinant or synthetic nucleic acid molecules, procedures, animal studies, laboratory locations, containment, or other risk-relevant elements are reviewed before implementation.

A five-year cycle also aligns more closely with the evolution of many funded research programs. New grants, competitive renewals, changes in scientific direction, and changes in personnel or

facilities frequently generate amendments or updated registrations during that period. Conducting a mandatory de novo review at three years may require an investigator to complete a full renewal shortly before a grant renewal or new project.

Mandatory de novo review every three years would substantially increase workload for investigators, BSOs, IBC staff, committee members, and institutional officials. Much of this additional effort would involve reconstructing and re-reviewing registrations for research that has not materially changed. The draft policy does not identify a biosafety benefit that would result from repeating a comprehensive review of unchanged work two years earlier than under a five-year grant review cycle.

The consequences associated with a lapse in approval may further shorten the practical renewal cycle. To prevent a registration from expiring because of an incomplete submission, investigator delay, committee scheduling, or the need for revisions, institutions may need to begin the renewal process many months before the three-year expiration date. The resulting operational cycle could approach two years, further increasing repetitive administrative review without a corresponding improvement in safety.

NIH should use a risk-based renewal framework that distinguishes unchanged research from research involving material scientific or biosafety changes. When the principal investigator confirms that the research remains unchanged, a BSO or qualified IBC delegate should be permitted to review the registration, verify the existing risk assessment and containment conditions, and renew the approval. The delegate should refer the registration to the convened IBC when the research has materially changed, the risk assessment is no longer adequate, relevant standards or best practices have changed, significant compliance concerns exist, or the reviewer otherwise determines that full committee review is warranted.

Mass General Brigham recommends the NIH:

- Permit IBC approvals for up to five years.
- Permit a BSO or other qualified IBC delegate to approve unchanged research after confirming that the risk assessment, containment, and approval conditions remain appropriate.
- If NIH retains the three-year maximum, permit streamlined delegated renewal of unchanged research rather than requiring a de novo review.
- Authorize temporary administrative extensions when a complete renewal was submitted before expiration and institutional review remains in progress.
- Preserve existing approvals through their current expiration dates rather than requiring early renewal solely to conform to the new policy.

ESTABLISH CLEAR, RISK-BASED THRESHOLDS FOR IMMEDIATE NIH INCIDENT NOTIFICATION

The draft policy requires institutions to notify NIH within 24 hours, or as soon as the institution becomes aware, of incidents considered to pose a significant risk to human health. The specified

categories include a confirmed or potential laboratory-acquired infection; a loss of containment or release with potential community risk; incidents at BSL-3/ABSL-3 or BSL-4/ABSL-4, including certain potential exposures, facility or equipment failures, and inventory or security issues; BSL-2/ABSL-2 exposures requiring agent-specific treatment beyond basic first aid; and compliance violations such as failure to obtain or maintain required IBC or NIH approval.

Mass General Brigham supports immediate notification when an incident presents a credible and significant risk of infection, transmission, environmental release, or harm to the community. However, several of the proposed thresholds are broad or undefined and could require immediate reporting before the institution has enough information to determine whether an event presents a significant risk.

Terms such as "potential laboratory-acquired infection," "potential community risk," "potential exposure," "agent-specific treatment," and "compliance violation" require objective definitions. Without clear thresholds, institutions may be required to report events based on a theoretical possibility rather than a reasonable assessment of likelihood and consequence. This could result in over-reporting of precautionary medical evaluations, minor deviations, contained equipment failures, or events for which subsequent investigation determines that no meaningful exposure or release occurred.

A potential laboratory-acquired infection should not include every illness that occurs following work with a biological agent. The threshold should require a reasonable basis to suspect a relationship between the illness and the individual's laboratory activities, considering the agent, symptoms, incubation period, exposure circumstances, and available occupational health assessment. Immediate notification may appropriately occur before causation is confirmed, but the initial assessment should establish that laboratory acquisition is reasonably plausible rather than merely possible.

Similarly, seeking medical evaluation or receiving prophylaxis does not necessarily establish that a meaningful exposure occurred. Medical professionals may recommend evaluation or precautionary treatment because information is incomplete, because the consequences of an unlikely infection could be serious, or because institutional procedures intentionally use conservative criteria. The current policy already recognizes this distinction for treatment related to possible adventitious agents, which is not reportable unless a laboratory-acquired infection results. NIH should apply a consistent principle to other precautionary evaluations and treatments.

The requirement to report potential releases involving facility or equipment failures at BSL-3/ABSL-3 or BSL-4/ABSL-4 also requires clarification. A failure of one component does not necessarily result in a loss of containment, particularly when redundant systems function as designed. Immediate notification should focus on failures that compromise containment or create a credible risk to personnel, the public, or the environment. Routine equipment malfunctions that

remain contained and are corrected through established procedures should be documented and reviewed institutionally but should not automatically require federal notification.

The treatment of compliance violations is also overly broad. Failure to obtain or maintain IBC approval is significant when covered research is conducted without required approval or after approval has expired. However, not every administrative discrepancy or delay materially compromises biosafety oversight. NIH should distinguish substantive noncompliance from administrative errors that are promptly corrected and do not affect containment, personnel safety, public health, or the environment.

The 24-hour period should begin when an appropriate institutional official, such as the BSO, IBC Chair, IBC office, or institutional official, has sufficient information to reasonably determine that the event meets the NIH reporting criteria. An incident may first be reported to a supervisor, Occupational Health, animal care personnel, facilities staff, or another institutional office without enough information to identify it as a reportable biosafety event. Starting the reporting period at the time of the underlying event, or when any institutional employee first becomes aware of it, would create an uncertain and potentially unworkable standard.

Mass General Brigham recommends the NIH:

- Limit 24-hour notification to incidents presenting a credible and significant risk of infection, transmission, environmental release, or material loss of containment.
- Define "potential laboratory-acquired infection" as an illness or condition for which laboratory acquisition is reasonably plausible based on an initial occupational health and biosafety assessment.
- Clarify that precautionary medical evaluation, diagnostic testing, vaccination, or prophylaxis does not independently make an event reportable when a meaningful exposure is not reasonably suspected.
- Define "potential community risk" using objective considerations such as loss of primary and secondary containment, agent transmissibility, environmental persistence, exposure pathway, quantity released, and effectiveness of the immediate response.
- Limit immediate reporting of facility or equipment failures to failures that compromise containment or create a credible risk to personnel, the public, or the environment.
- Clarify that failure of one component does not constitute a reportable release when redundant containment systems function as intended and no credible exposure or release occurs.
- Limit federally reportable compliance violations to substantive violations that materially compromise biosafety oversight or result in covered research being conducted without required approval or containment.
- Permit institutions to document and correct minor administrative discrepancies without immediate federal notification when the discrepancy does not affect safety or oversight.

- Start the 24-hour period when the BSO, IBC Chair, IBC office, institutional official, or another designated institutional authority has sufficient information to reasonably determine that the event meets NIH reporting criteria.
- Require the initial notification to include only information reasonably available at the time of reporting.
- Use a tiered framework that distinguishes immediate NIH notification, routine NIH reporting, and institution-only documentation.
- Permit periodic aggregate reporting of lower-risk events that NIH determines would provide useful surveillance information but do not warrant immediate notification.

CLARIFY THE EXCLUSION OF WILD-TYPE RG1 BIOLOGICAL AGENTS

The draft policy is unclear regarding whether research involving wild-type Risk Group 1 biological agents is subject to the policy. Section IV-3 states:

"[Note: Experiments involving RG1 wild-type biological agents are not subject to this Policy.]"

This exclusion is not clearly reflected in the policy's scope or definitions. Section II defines research involving biohazards to include research involving wild-type bacteria, viruses, fungi, or parasites that "cause disease in humans," and the definition of "biological agent" uses similarly broad language. Some organisms generally classified as RG1 may nevertheless have been associated with rare disease, opportunistic infection, or disease in unusually susceptible individuals. As written, the broader scope and definitional language could therefore be interpreted to include agents that Section IV-3 states are excluded.

To resolve this uncertainty, NIH should align the scope, definitions, and review categories by using language consistent with the BMBL and established Risk Group framework. Mass General Brigham recommends that the NIH define covered wild-type biological agents as:

"Wild-type biological agents that are associated with disease in healthy adult humans."

This language would more clearly distinguish covered wild-type agents from RG1 agents. It would also preserve Section IV-3 exclusion without relying on a note that could conflict with the broader operative language elsewhere in the policy.

Mass General Brigham recommends the NIH:

- Revise the scope and definition of "biological agent" to refer to wild-type biological agents "associated with disease in healthy adult humans."
- State expressly in the scope section that research involving wild-type RG1 biological agents is not subject to the policy.
- Apply the RG1 exclusion consistently throughout the scope, definitions, and review categories rather than placing the exclusion only in a note under Section IV-3.

- Clarify that the rare occurrence of opportunistic disease or disease in an unusually susceptible person does not necessarily bring an otherwise RG1 wild-type agent within the scope of the policy.
- Remove the bracketed note concerning wild-type RG1 biological agents from Section IV-3 and incorporate the exclusion directly and consistently into the policy's scope, definitions, and exclusions section.

CLARIFY THE REVIEW CATEGORY FOR PRIMARY CELLS THAT MAY CONTAIN ADVENTITIOUS AGENTS

Section IV-2 requires full IBC review of research involving "primary cells that may be contaminated with adventitious agents." The draft does not define "primary cells," "adventitious agents," or the degree of likelihood necessary to conclude that primary cells may be contaminated.

This requirement also appears inconsistent with the policy's risk-based review structure. Section IV-2 generally requires full committee review for research involving RG3 and RG4 wild-type biological agents, while Section IV-3 permits delegated review of research involving RG2 wild-type biological agents. As written, however, primary cells that may contain an RG2 adventitious agent would require full committee review. This could subject cells that are only potentially contaminated with an RG2 agent to a higher level of review than research conducted directly with the same wild-type agent.

The treatment of HIV requires clarification. Because HIV is classified as an RG3 biological agent, a broad interpretation of "may be contaminated" could require full committee review of virtually all primary human cells based solely on the possibility that the donor may have been infected with HIV. This would be inconsistent with the established approach of treating human blood, tissues, and other potentially infectious materials as though they may contain bloodborne pathogens and applying appropriate universal precautions, rather than presuming that every specimen contains an RG3 agent.

Routine primary human cells should not require full committee review solely because HIV or another bloodborne pathogen cannot be excluded with absolute certainty. Unless the cells are known or reasonably suspected to be HIV-positive, originate from a population with a substantial likelihood of HIV infection, or will undergo procedures that could propagate or concentrate HIV, the research should be eligible for delegated review. The use of universal precautions and appropriate containment should be considered part of the risk mitigation supporting delegated review.

The required review pathway should reflect the identity and Risk Group of any known or reasonably suspected adventitious agent, the likelihood that the agent is present, the available donor screening or product-testing information, and whether the proposed procedures could propagate, amplify, concentrate, or aerosolize the agent.

Mass General Brigham recommends the NIH:

- Define "primary cells" and "adventitious agents."
- Clarify whether HIV, hepatitis viruses, and other bloodborne pathogens potentially present in donor-derived materials are considered adventitious agents.
- Clarify that the theoretical possibility of HIV contamination does not automatically require full committee review of all primary human cells.
- Permit delegated review of routine primary human cells handled under universal precautions and applicable bloodborne-pathogen requirements.
- Permit delegated review when primary cells may contain an RG2 agent, consistent with the delegated-review pathway for work conducted directly with wild-type RG2 biological agents.
- Reserve full committee review for primary cells known or reasonably suspected to contain an RG3 or RG4 agent, including cells from donors known to be infected, or for procedures likely to propagate, amplify, concentrate, or aerosolize such an agent.
- Explain how donor screening, population prevalence, product testing, commercial sourcing, repository characterization, fixation, validated inactivation, and other processing affect the review pathway.
- Align the review level for potentially contaminated primary cells with the review level that would apply to direct research involving the known or reasonably suspected agent.

CLARIFY BSO RESPONSIBILITY FOR INSTITUTIONAL INSPECTION PROGRAMS

The draft policy requires an institution to appoint a Biological Safety Officer when it conducts research at BSL-3 or BSL-4 or conducts research involving gene drive modified organisms. The draft then identifies "conducting periodic inspections" as one of the BSO's duties, including inspections to ensure that biocontainment facilities and equipment function properly, biosafety standards are followed, and IBC approval conditions are implemented.

The policy should clarify both the scope of the inspection requirement and the nature of the BSO's responsibility. Periodic inspections specifically required under the NIH policy should focus on BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories, where the policy requires appointment of a BSO and where facility systems, specialized containment equipment, and operational practices warrant formal recurring verification. Institutions may use inspections for BSL-1/ABSL-1 and BSL-2/ABSL-2 research as part of their broader institutional biosafety programs, but the appointment of a BSO should not, by itself, create an additional federal inspection requirement for every lower-containment laboratory.

This distinction is particularly important because some institutions appoint a BSO even when the policy does not require one. Institutions should not be subject to additional federal requirements solely because they voluntarily establish a more comprehensive biosafety program or designate a

BSO to support lower-containment research. Such an outcome could discourage institutions from voluntarily appointing qualified biosafety professionals.

The phrase "conducting periodic inspections" could also be interpreted to require the designated BSO to personally inspect every applicable laboratory. That approach would be impractical for large or geographically distributed institutions and would not necessarily improve inspection quality. Institutions commonly conduct inspections through qualified biosafety, environmental health and safety, research safety, animal safety, infection control, facilities, or other technical personnel working within an established institutional inspection program.

The BSO should retain oversight of the inspection process, including responsibility for establishing appropriate inspection standards, ensuring that inspections are performed by qualified personnel, reviewing significant findings, monitoring corrective actions, and reporting material deficiencies to the IBC and institution. The BSO should not be required to personally conduct each inspection.

The draft already recognizes a comparable delegation model by allowing the IBC's periodic review of approved research to be delegated to the BSO "or other staff, as appropriate." The inspection provisions should provide similar flexibility.

Mass General Brigham recommends the NIH:

- Clarify that the recurring inspection requirement under the policy applies to BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories.
- Clarify the inspection requirements applicable to research involving GDMOs when that research is conducted below BSL-3/ABSL-3.
- Clarify that the BSO must oversee the institutional inspection process but is not required to personally conduct every inspection.
- Permit qualified biosafety, environmental health and safety, research safety, animal safety, infection control, facilities, or equivalent personnel to conduct inspections under BSO oversight.
- Require the BSO to establish or approve inspection standards, review significant findings, ensure appropriate corrective-action follow-up, and report significant deficiencies to the IBC and institution.
- Avoid imposing additional requirements on institutions solely because they voluntarily appoint a BSO or maintain a biosafety program that exceeds the minimum federal requirements.

SYSTEM-LEVEL BIOSAFETY ASSURANCES FOR INTEGRATED HEALTH SYSTEMS

The draft requires each institution to submit a Biosafety Assurance describing its lines of authority, responsible personnel, biosafety procedures, IBC roster, meeting minutes, incident reports, training, and relevant research activities. The policy does not explain how the

requirement applies when multiple hospitals or legal entities rely on a common IBC, centralized biosafety administration, and shared governance structure.

. Requiring each participating hospital or legal entity to submit a separate Assurance containing the same IBC membership, governance procedures, policies, training systems, public records, and administrative information would create duplicative work without strengthening oversight.

NIH should permit an integrated health system, university system, or similarly structured research organization to submit one system-level Assurance when participating institutions operate under a common IBC and coordinated biosafety governance structure. The Assurance could identify each covered component institution and describe any institution-specific officials, BSOs, facilities, responsibilities, or local requirements while incorporating shared program elements once.

A system-level Assurance would provide NIH with a more accurate description of how an integrated biosafety program operates. It would also support consistent oversight across participating institutions while preserving accountability for institution-specific responsibilities.

Mass General Brigham recommends the NIH:

- Permit a single system-level Biosafety Assurance for an integrated health system or research organization operating a common IBC and centralized biosafety governance structure.
- Permit multiple hospitals, research institutions, and legal entities to be listed as component institutions under the system-level Assurance.
- Clarify which Authorized Organizational Representative may submit and certify the system-level Assurance.
- Replace “continuously updated” with a defined period for reporting material changes.
- Distinguish material changes requiring NIH notification from routine administrative updates maintained in institutional records or on public websites.

RETAIN ESTABLISHED EXEMPTIONS AND CREATE A MECHANISM FOR FUTURE EXCLUSIONS

The draft policy substantially expands federal biosafety oversight beyond research involving recombinant or synthetic nucleic acid molecules, but it does not include a dedicated section identifying research that is excluded from the policy. It also does not preserve the exemptions developed under Section III-F and Appendix C of the current NIH Guidelines.

The current exemptions incorporate decades of experience and risk-based determinations of research activities that do not present a significant risk to human health or the environment. Unless NIH has identified new evidence that an existing exemption no longer provides adequate protection, the exemption should be carried forward into the final policy.

The need to retain existing exemptions is particularly important because the draft policy broadly covers genetically modified cells, viruses, and organisms. Without an explicit exclusions section, routine activities involving well-characterized host-vector systems, established cell lines, transgenic rodents, and other commonly used research systems could require IBC approval even though the same activities are currently exempt from the NIH Guidelines.

The final policy should therefore include a dedicated "Exclusions" section that retains, at a minimum, the following existing exemptions should be included:

- Cells, viruses, or organisms genetically modified exclusively through the introduction of genetic material derived from the same species, when the resulting genetic material can occur through natural physiological processes.
- Prokaryotic organisms genetically modified with sequences consisting entirely of DNA from the same prokaryotic host, including its plasmids or viruses, when the genetic material is propagated only in that host or transferred to another host through well-established physiological processes.
- Eukaryotic cells or organisms genetically modified with sequences consisting entirely of DNA from the same eukaryotic host, including DNA derived from its mitochondria or plasmids, when the genetic material is propagated only in that host or in a closely related strain of the same species.
- Cells or organisms genetically modified through the exchange of DNA between species that are known to exchange DNA through well-established physiological processes.
- Well Characterized tissue-culture cells genetically modified with recombinant or synthetic nucleic acid molecules, provided that the modification does not introduce or produce an infectious biological agent, biological toxin, gene-drive system, or other biological hazard covered by the policy.
- *Escherichia coli* K-12 strains genetically modified using NIH-certified K-12 host-vector systems, provided that the host-vector system and introduced sequences satisfy the conditions of the applicable exemption.
- *Saccharomyces cerevisiae* and *Saccharomyces uvarum* strains genetically modified using NIH-certified *Saccharomyces* host-vector systems, provided that the host-vector system and introduced sequences satisfy the conditions of the applicable exemption.
- *Bacillus subtilis* or *Bacillus licheniformis* strains genetically modified using characterized host-vector systems, provided that the strains do not revert to a spore-forming phenotype and satisfy the conditions of the applicable exemption.
- Gram-positive organisms genetically modified using specified naturally occurring extrachromosomal elements, provided that the elements are maintained in their natural hosts or transferred to another host through well-established physiological processes and the applicable conditions of the current exemption are satisfied.
- Transgenic rodents purchased or transferred for research purposes, provided that the animals contain no genetic modification derived from a Risk Group 3, Risk Group 4,

restricted, or otherwise covered higher-risk biological agent and otherwise satisfy the conditions of the current exemption.

- Rodents produced through the breeding of two transgenic strains, or through the breeding of a transgenic strain with a wild-type strain, provided that the resulting animals can be maintained under ABSL-1 containment and the breeding does not create a novel or increased biosafety risk.

NIH should also consider extending the exclusions to established low-risk model organisms and laboratory strains, including *Caenorhabditis elegans*, *Drosophila melanogaster*, and *Escherichia coli* B21, when the modification does not introduce a biological agent, toxin, gene-drive system, increased pathogenicity, increased transmissibility, or another identifiable biosafety hazard. These organisms and strains have long histories of research use and may present risks comparable to or lower than transgenic rodents already addressed through the current exemptions.

The final policy should distinguish federal exclusions from institutional discretion. An activity excluded from the federal policy may remain subject to institutional review or applicable state or local requirements. However, an institution's decision to review excluded research should not make the activity subject to federal Biosafety Assurance, public-minutes, federal incident-reporting, or enforcement requirements.

The exclusions section should also retain a general mechanism through which NIH may add, modify, or withdraw exclusions as scientific knowledge and research technologies evolve. The current NIH Guidelines permit NIH to determine, following appropriate notice and opportunity for public comment, that classes of experiments do not present a significant risk to health or the environment. The broader scope of the proposed policy makes such a mechanism even more important. Without it, well-characterized and demonstrably minimal-risk activities could remain subject to federal approval, reporting, public-disclosure, recordkeeping, and enforcement requirements merely because they were not anticipated when the final policy was issued.

Mass General Brigham recommends the NIH:

- Add a dedicated "Exclusions" section to the final policy.
- Retain the existing exemptions in Section III-F and Appendix C of the current NIH Guidelines unless NIH identifies a specific, evidence-based reason to modify or withdraw an exemption.
- Preserve the existing certified host-vector system exemptions, tissue-culture exemptions, and qualifying transgenic-rodent purchase, transfer, and breeding exemptions.
- Consider excluding established low-risk model organisms, including *Caenorhabditis elegans* and *Drosophila melanogaster*, when the modification does not introduce an identifiable biosafety hazard.

- Establish a formal, transparent mechanism for adding, modifying, or withdrawing exclusions based on accumulated experience, scientific evidence, and technological development.
- Permit institutions, professional organizations, and other interested parties to request evaluation of a category of research for exclusion.
- Publish exclusion and equivalency determinations in a centralized, searchable repository that institutions may rely upon.

CLARIFY THE REQUIREMENT TO REPORT DELEGATED APPROVALS "IN FULL" IN PUBLIC MINUTES

Section IV-3 permits an individual IBC member or subgroup of IBC members to review and approve minor amendments and specified categories of lower-risk research. The draft then requires the IBC to be notified when a delegated approval is granted and requires the approval to be "reported in full" at the next scheduled IBC meeting for inclusion in the minutes.

The phrase "reported in full" is not defined. It is unclear whether NIH intends the minutes to include a complete protocol summary and risk assessment for every delegated approval or whether a structured listing of the approval would satisfy the requirement. This ambiguity is particularly significant because the draft minutes template confirms that IBC minutes must be posted on a public-facing institutional website.

Mass General Brigham already presents administrative approvals to the IBC for comment and questions. For example, meeting minutes document presentation of the month's administrative approvals as part of other committee business. The final policy should preserve institutional flexibility to use this type of consent-agenda or summary process.

Requiring protocol-level documentation for every delegated approval would substantially reduce the operational value of delegated review. Institutions may process a large number of lower-risk registrations and minor amendments through delegated pathways. Preparing full public summaries of every delegated action would increase staff workload, lengthen meeting materials and minutes, and require additional review for confidential, proprietary, privacy-sensitive, or security-sensitive information.

The requirement could also blur the distinction between delegated and full committee review. Delegated review is intended to provide a proportionate and efficient pathway for minor amendments and defined categories of lower-risk research. If every delegated approval must subsequently be presented and documented at the same level of detail as research reviewed by the convened committee, much of the efficiency gained through delegated review would be lost.

The final policy should require sufficient information for the IBC and the public to understand the nature and volume of delegated actions without requiring protocol-level disclosure. A structured listing or consent agenda could identify the institutional registration number, general

category of research, type of action, type of biological material, containment level, approval date, and any material conditions. The IBC should retain the ability to request additional information or refer an item for discussion when warranted.

Minor amendments also require separate consideration. Administrative changes such as additions or removals of personnel, changes in contact information, corrections, or other changes that do not affect the risk assessment should not require individual reporting in public minutes. NIH should distinguish administrative updates from scientific amendments approved through delegated review.

Mass General Brigham recommends the NIH:

- Define what information must be included for a delegated approval to be "reported in full."
- Clarify that a structured list, consent agenda, or attached report may satisfy the reporting requirement.
- Permit institutions to report each delegated approval using the institutional registration number, general research category, type of submission or amendment, broad biological materials, containment level, approval date, and material conditions.
- Clarify that reporting a delegated approval does not require the convened IBC to reconsider, ratify, or vote on the approval unless the IBC determines that additional review is warranted.
- Permit the IBC to request additional information or elevate delegated approval for discussion when necessary.
- Exclude purely administrative updates that do not affect the biosafety risk assessment from individual reporting in public minutes.
- Revise "reported in full" to "reported to the IBC through a structured summary sufficient to document the delegated action."

LIMIT THE POLICY'S TOXIN DEFINITION TO TOXINS WITH AN LD50 BELOW 100 NANOGRAMS PER KILOGRAM

The draft policy defines a toxin broadly as "a protein or peptide produced by living organisms that causes harm in humans." Section II includes toxins within the scope of the policy without establishing a potency threshold. Section IV-3 then permits delegated review of biological toxin proteins that are not on the Select Agent list. This language could bring nearly any harmful protein or peptide within federal IBC oversight, regardless of its toxicity, quantity, concentration, route of exposure, or realistic potential to cause harm under laboratory conditions.

The absence of a potency threshold is inconsistent with the risk-based approach NIH has applied under the current NIH Guidelines. Section III-B-1 uses an LD50 of less than 100 nanograms per kilogram body weight to identify genes encoding exceptionally potent toxin molecules.

Examples include genes encoding botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin.

This established threshold provides an objective and familiar boundary for identifying toxins of sufficient potency to warrant specialized federal biosafety oversight. Retaining the threshold would also avoid extending the policy to the large number of ordinary proteins and peptides that can cause harm at sufficiently high doses but do not present the type of biosafety risk that warrants federal IBC regulation.

The NIH should therefore retain the established LD50 threshold of less than 100 nanograms per kilogram to identify exceptionally potent toxins and genes encoding exceptionally potent toxins that warrant heightened federal oversight. Toxins above that threshold should be excluded from federal IBC oversight or assigned to delegated review according to potency, quantity, concentration, route of exposure, physical form, and the proposed manipulation.

Mass General Brigham recommends the NIH:

- Retain the established threshold of a human LD50 of less than 100 nanograms per kilogram body weight.

PLANT-DERIVED TOXINS AND TOXIN-PRODUCING PLANT CELLS

The draft policy defines a toxin as a protein or peptide produced by a living organism that causes harm in humans. Although plants are excluded from the genetic-modification components of the policy's scope, the toxin definition does not expressly exclude proteins or peptides produced by plants.

NIH should separately clarify the status of:

1. Purified plant-derived protein or peptide toxins.
2. Intact plants that produce toxins.
3. Plant tissues and plant cell cultures that produce toxins.
4. Genetically modified plant cells engineered to express toxins.
5. Nonprotein and nonpeptide toxic compounds produced by plants.

The final policy should explain whether research with plant cells producing a covered toxin constitutes research with a toxin, research involving an excluded plant, or both.

TOXIC PEPTIDES AND "BIOLOGICAL TOXIN PROTEINS"

The draft definition of toxin includes both proteins and peptides. Section IV-3, however, permits delegated review only for "biological toxin proteins" not on the Select Agent list. Read literally, a non-Select Agent toxic peptide may require full committee review solely because the delegated category refers only to proteins.

If NIH intends delegated review to be available for both categories, Section IV-3 should state:

"Toxins not on the Select Agent list."

Review level should reflect the actual risk, including potency, quantity, concentration, physical form, route of exposure, aerosol potential, experimental manipulation, and capacity for intracellular access, rather than whether the toxin is categorized as a protein or peptide.

GRANDFATHERING AND IMPLEMENTATION

The draft policy would become effective six months after publication and would apply to ongoing and new research. The draft does not clearly explain how existing approvals will transition to the new framework.

Mass General Brigham recommends the NIH:

- Allow existing IBC approvals to remain valid through their current expiration dates.
- Avoid requiring institutions to conduct de novo review of their entire active portfolio within the implementation period.
- Phase in the Biosafety Assurance, review-cycle changes, registration conversion, reporting systems, and public-disclosure requirements.
- Publish final templates, definitions, reporting criteria, technical specifications, and implementation guidance before the transition period begins.
- Provide sufficient time for institutions to modify electronic systems, policies, forms, training, websites, and reliance arrangements.
- Establish a corrective-action period before imposing institution-level enforcement for implementation-related deficiencies.

DEFINITION AND CONSISTENT USE OF GDMO

The draft uses "GDMO," "gene drive modified organism," and "gene drive modified biological agent" without clearly establishing whether these terms are synonymous. The distinction is important because "organism" and "biological agent" may not have identical meanings under the draft definitions.

NIH should define GDMO at its first use and in the general definitions and use one term consistently throughout the policy. The definition should clarify whether the category includes animals, arthropods, microorganisms, viruses, cells, and other biological systems. It should also clarify whether the definition requires a functional gene drive or includes organisms used to develop, test, or contain individual gene-drive components.

CLARIFY AND STREAMLINE NIH REVIEW OF EMERGING, NOVEL, AND ZOONOTIC AGENTS

Section IV-1 requires NIH and IBC approval before initiation of research involving an emerging, novel, or zoonotic agent when neither a Risk Group classification nor a recommendation for minimum containment is available in the BMBL. The IBC must petition NIH for a determination of the minimum containment level and may not approve the research until NIH and other applicable authorities authorize it. The request must include a detailed description of the agent, modifications, biological systems, experimental manipulations, reagents, proposed containment, institutional risk assessment, and supporting data.

Mass General Brigham supports federal oversight when an agent presents substantial uncertainty that cannot be resolved through an institutional risk assessment. However, the proposed requirement is broad and could delay research involving an agent that is absent from the BMBL for reasons unrelated to elevated risk. The BMBL does not provide a Risk Group classification or minimum containment recommendation for every known microorganism, recently identified agent, zoonotic agent, attenuated strain, or novel construct.

"Zoonotic" is not inherently synonymous with high risk or high uncertainty. An agent may be capable of animal-to-human transmission and still present a well-characterized or limited risk. Similarly, an emerging agent may be newly identified but closely related to a known agent with an established Risk Group and containment recommendation. Mandatory NIH review should depend on the degree of uncertainty and potential severity of the agent, not solely on whether the agent is categorized as emerging, novel, or zoonotic. As an example, our research portfolio includes research on *Arcanobacterium* pyogenes, a zoonotic agent not covered by the BMBL. Thus our research would not continue upon adoption of the policy while the NIH or the CDC makes a determination on this agent.

The current NIH risk-assessment framework recognizes that unlisted agents may be assessed using their known and potential properties, their relationship to listed agents, and experiment-specific factors including pathogenicity, infectious dose, environmental stability, route of spread, communicability, quantity, available countermeasures, and proposed manipulations. The new policy should preserve a meaningful role for institutional risk assessment rather than requiring NIH review whenever an agent is not specifically listed in the BMBL.

When NIH review is required, the policy should permit an institution to approve work at a conservatively selected containment level while the federal determination is pending. An IBC may be able to determine that an unclassified agent can be safely handled at a containment level equal to or greater than that used for a closely related agent. Prohibiting all work during NIH review may delay time-sensitive diagnostic, surveillance, public-health, or emerging-infectious-disease research without improving safety.

NIH should also establish a process for publishing and reusing its determinations. The draft requires NIH to publish approved lower-containment determinations for RG3 and RG4 agents,

but it is less explicit about publishing all determinations for emerging, novel, or zoonotic agents. NIH should maintain a searchable repository that institutions may rely upon when proposed work involves the same agent or a materially equivalent agent, construct, attenuation, and experimental procedure.

Finally, NIH determinations should not remain indefinitely separate from the BMBL or other authoritative federal classifications. When CDC, NIH, the BMBL, the Federal Select Agent Program, or another appropriate federal source subsequently assigns a Risk Group or minimum containment recommendation, NIH should review, update, or retire its earlier determination. This will prevent conflicting classifications and unnecessary repeated federal petitions.

Mass General Brigham recommends the NIH:

- Define "emerging," "novel," and "zoonotic" using objective and risk-based criteria.
- Clarify that classification as emerging, novel, or zoonotic does not, by itself, establish that an agent presents elevated risk requiring federal review.
- Limit mandatory NIH review to agents for which the absence of an established classification creates material uncertainty regarding appropriate containment or presents the potential for serious human, community, or environmental harm.
- Permit IBCs to assign containment without prior NIH approval when adequate information exists to support a documented risk assessment using a closely related agent, published evidence, or other authoritative information.
- Permit institutions to initiate research at conservatively selected containment while NIH review is pending, unless NIH identifies a specific reason the research should not proceed.
- Establish target timelines for NIH acknowledgment, completeness review, requests for additional information, and final determination.
- Develop a streamlined review pathway for an agent that is closely related to an agent with an established Risk Group or BMBL containment recommendation.
- Publish all NIH determinations involving emerging, novel, or zoonotic agents in a public, searchable repository.
- Permit institutions to rely on a prior NIH determination involving the same or a materially equivalent agent, construct, attenuation, and experimental activity.
- Coordinate determinations with CDC and other relevant federal agencies to reduce duplicative review.
- Establish a process to review, update, supersede, or retire an NIH determination when the BMBL or another authoritative federal source subsequently assigns a Risk Group or minimum containment recommendation.

CLINICAL-RESEARCH COVERAGE

The draft policy identifies categories of clinical research requiring IBC review, including products capable of shedding, replicating, or integrating, products involving higher-risk manipulations, and deliberate administration of RG2 or higher wild-type agents.

Mass General Brigham recommends the NIH:

- Whether "capable of shedding, replicating, or integrating" refers to the final administered product, residual manufacturing components, or the original method used to manufacture or modify the product.
- The meaning of "higher-risk manipulation."

The final policy should also distinguish federally required clinical oversight from broader clinical research that an institution elects to review under institutional or local authority.

CONCLUSION

Mass General Brigham supports NIH's effort to modernize biosafety oversight and agrees that the final policy should establish a comprehensive, transparent, accountable, and risk-based framework for research involving biohazards. Many elements of the proposed framework are consistent with the broad institutional biosafety oversight that Mass General Brigham already provides. However, several provisions require clarification or revision to ensure that the final policy advances biosafety without discouraging incident reporting, interrupting compliant research, requiring repetitive review of unchanged activities, or imposing federal requirements that are disproportionate to the risks presented.

Our highest priority recommendation is that NIH remove the requirement for institutions to publicly post individual incident reports. Effective biosafety programs depend on prompt reporting, candid investigation, and meaningful analysis of contributing factors. Public disclosure of event-specific reports may discourage personnel from reporting minor incidents, suspected exposures, and near misses and may permit identification of affected individuals even when direct identifiers are removed. NIH can more effectively advance transparency and shared learning through aggregated, deidentified incident analyses and annual national summaries.

Our second highest priority is replacing mandatory three-year de novo review with a risk-based renewal framework. This requirement would likely have the greatest operational impact on the institutional biosafety program and would require substantial new resources from investigators, biosafety officers, IBC staff, committee members, and institutional leadership. Much of the additional effort would be directed toward reconstructing and rereviewing registrations for research that has not materially changed. Permitting approvals of up to five years, supported by annual investigator certification, prospective review of risk-relevant changes, and delegated renewal of unchanged research, would maintain rigorous continuing oversight while allowing

institutional resources to remain focused on new research, substantive amendments, higher-risk activities, incident response, inspections, training, and other work that directly advances biosafety.

Mass General Brigham appreciates NIH's consideration of these comments and welcomes continued engagement with NIH as the final policy and implementation materials are developed. If you have any questions, please contact Aimee Kasenga, Director of Public Policy, Office of Government Affairs, at akasenga@mgb.org. Thank you for this opportunity to provide feedback.

Sincerely,

Paul Anderson, MD, PhD
Chief Academic Officer
Mass General Brigham

Joseph El Khoury, MD, FIDSA
Chair of the Institutional Biosafety Committee
Mass General Brigham

Ryan Schlimgen, PhD
Senior Director of Biosafety
Research Compliance
Mass General Brigham

135. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed expansion of biosafety oversight should be guided by scientifically justified, evidence-based risk assessments rather than broad definitions that unnecessarily capture routine, low-risk research. For laboratories working with primary human cells, genetically modified cell lines, transgenic animals, viral vectors, and infectious agents, an overly expansive or ambiguous definition of biohazards could result in inconsistent institutional interpretations, duplicative IBC reviews, and unnecessary delays. NIH should clearly distinguish established biological hazards from hypothetical or negligible risks and establish explicit criteria for determining which activities require formal IBC oversight. The policy should also clarify the boundaries between IBC, IACUC, and other institutional oversight responsibilities to avoid regulatory gaps or overlapping requirements. Importantly, investigators should not be held personally accountable for institutional failures to interpret, implement, or enforce biosafety requirements, particularly when they lack authority over institutional infrastructure or administrative decisions. NIH should ensure that expanded oversight is proportional to demonstrable risk, consistently implemented across institutions, and supported by clear guidance that protects both research safety and investigators' ability to conduct science.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support a tiered, risk-based approach to biosafety oversight, provided that risk classifications are scientifically justified, clearly defined, and consistently applied across institutions. NIH should establish uniform federal criteria for risk assessment and oversight requirements, while allowing local IBCs to evaluate institution-specific conditions without imposing additional restrictions unsupported by demonstrable biological risks. Excessive local discretion may lead to inconsistent interpretations, unnecessary protocol reviews, prolonged approval timelines, and administrative requirements that vary substantially between institutions. Importantly, institutions should remain accountable for biosafety infrastructure, regulatory interpretation, and timely review processes rather than transferring these responsibilities and associated liabilities to Principal Investigators. Investigators should not face research delays, missed grant milestones, funding consequences, or professional and legal exposure resulting from inconsistent institutional decisions or administrative failures beyond their control. NIH should establish clear mechanisms for resolving disagreements between investigators and institutional oversight committees,

including access to authoritative federal guidance. Effective tiered oversight should ensure that higher-risk research receives appropriate scrutiny while low-risk research proceeds efficiently, without compromising safety or unnecessarily obstructing scientific progress.

3. Continued utility of Risk Groups: Risk Groups (RGs) should remain a useful starting point for biosafety assessment, but they should not independently determine containment requirements, particularly when biological agents are genetically modified. Genetic modifications may alter pathogenicity, host range, transmissibility, or other characteristics relevant to biological risk. Conversely, not all genetic modifications increase risk, and additional containment requirements should not be imposed solely because an agent has been genetically modified. NIH should adopt an evidence-based framework that considers the properties of the modified agent, the experimental procedures, potential exposure routes, and available safeguards when determining appropriate Biosafety Levels (BSLs), consistent with the principles outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL). NIH should establish clear, standardized federal guidance to minimize inconsistent interpretations among institutional biosafety committees and prevent unnecessary restrictions on routine research involving viral vectors, genetically modified cells, and transgenic animals. Institutions should remain responsible for applying these standards consistently, providing appropriate biosafety infrastructure, and resolving regulatory ambiguities rather than transferring these responsibilities and associated risks to Principal Investigators. The objective should be to ensure that biosafety requirements reflect actual experimental risks while enabling research to proceed safely and without avoidable administrative delays.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary compliance among institutions not subject to the proposed biosafety policy by providing clear, accessible, and standardized guidance, training resources, and technical assistance rather than creating additional administrative or regulatory burdens. Voluntary participation should be supported through institutional capacity building, including access to biosafety expertise, risk assessment tools, and established best practices. Importantly, NIH should distinguish between institutional responsibilities and those of individual investigators, ensuring that voluntary compliance does not result in institutions transferring additional administrative obligations, financial costs, or legal liabilities to Principal Investigators. Institutions choosing to adopt the policy should be responsible for providing the necessary infrastructure, qualified personnel, and oversight mechanisms. NIH should also establish clear boundaries between voluntary best practices and mandatory requirements to prevent inconsistent institutional interpretations or the gradual conversion of voluntary recommendations into de facto obligations. The objective should be to promote a consistent culture of biosafety across the research community while preserving institutional accountability, proportionality of oversight, and investigators' ability to conduct research without unnecessary administrative barriers or professional risks.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed Incident Reporting and IBC Meeting Minutes Templates should prioritize biosafety accountability while protecting investigators from unnecessary professional, legal, and financial risks. NIH should clearly distinguish institutional compliance failures, equipment or infrastructure deficiencies, and administrative errors from actions directly attributable to investigators. Incident reports should document the circumstances, contributing factors, corrective actions, and institutional responsibilities without automatically assigning blame to PIs. Publicly accessible reports and meeting minutes should exclude personally identifiable information, unpublished scientific discoveries, proprietary methodologies, patentable inventions, and

other confidential research details that are not essential to public safety. NIH should require institutional review of reports for accuracy and confidentiality, with opportunities for affected investigators to identify factual errors or sensitive information before public disclosure, without delaying mandatory reporting. Investigators should not face reputational damage, funding consequences, or personal legal expenses resulting from institutional failures or inappropriate disclosure of confidential information. NIH should also establish clear procedures for correcting inaccurate public records and responding to confidentiality breaches, including appropriate legal assistance and remediation. Ultimately, reporting should promote transparency, institutional accountability, and improvements in biosafety practices without creating unnecessary administrative burdens or exposing investigators to avoidable risks.

6. Other feedback relevant to this resource: Successful implementation of the proposed biosafety policy will require comprehensive, timely, and standardized training of NIH personnel, institutional biosafety officers, IBC members, and research administrators before the policy takes effect. A significant concern is the lag between NIH policy changes and the availability of clear, authoritative guidance, which creates inconsistent interpretations that propagate throughout research institutions and ultimately place unnecessary administrative burdens and risks on Principal Investigators. NIH should provide practical implementation resources, including standardized risk assessment criteria, clear distinctions between institutional and investigator responsibilities, guidance on coordinating IBC and IACUC approvals, and explicit procedures for resolving regulatory ambiguities. Dedicated communication channels between NIH and institutional compliance offices should ensure that institutions receive consistent instructions without transferring responsibility for interpreting policies to investigators. NIH should also establish reasonable review timelines, escalation mechanisms for administrative delays, and safeguards protecting investigators from professional, financial, or legal consequences arising from institutional compliance failures beyond their control. Implementation resources should include clear procedures for protecting confidential research information and addressing unauthorized disclosures. Most importantly, NIH should evaluate institutional readiness and staff competency before implementation rather than relying on investigators to resolve deficiencies in administrative systems. The ultimate objective should be to enable safe and timely scientific research while ensuring that institutions and NIH personnel remain accountable for their respective responsibilities.

136. Campus Safety Health and Environmental Management Association

I am responding: On behalf of an organization

Name: Robin Izzo

Name of Organization: Campus Safety Health and Environmental Management Association

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: CSHEMA-NIH-Comments.pdf

Description: PDF comment on the proposed policy on behalf of the Campus Safety Health and Environmental Management Association, the premier association for environmental health and safety leadership in higher education. CSHEMA represents institutions that range from large research-intensive universities with mature biosafety programs to smaller colleges that may have limited or no dedicated biosafety staff. Our members include biosafety professionals, environmental health and safety practitioners, and institutional leaders responsible for implementing biosafety requirements across diverse research and teaching environments.

Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards

Response to NOT-OD-26-112

October 12, 2026

Submitted Electronically

The Campus Safety, Health, and Environmental Management Association (CSHEMA) is the premier association for environmental health and safety leadership in higher education. CSHEMA represents institutions that range from large research-intensive universities with mature biosafety programs to smaller colleges that may have limited or no dedicated biosafety staff. Our members include biosafety professionals, environmental health and safety practitioners, and institutional leaders responsible for implementing biosafety requirements across diverse research and teaching environments.

CSHEMA appreciates NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions. **Due to such uncertainty in the final requirements, CSHEMA encourages NIH to provide an opportunity for public review and comment on the next draft before it is finalized.**

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." The policy should clarify whether precautionary post exposure prophylactic treatment is considered "agent-specific treatment". It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

6. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

CSHEMA recommends that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

Conclusion

CSHEMA supports NIH's goal of modernizing biosafety oversight and appreciates the draft's movement toward broader risk awareness, clearer incident thresholds, delegated review, and national safety learning. For the policy to succeed, however, modernization must strengthen the institutional systems that perform biosafety work rather than simply expand their obligations.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified

local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

CSHEMA respectfully requests that NIH revise the draft consistent with these recommendations, release complete implementation materials for public review, pilot key templates and processes, and provide a minimum 24-month phased implementation period. CSHEMA welcomes continued engagement and would be pleased to assist NIH in testing implementation resources or gathering additional institutional perspectives.

Sincerely,



Robin Izzo
President
Campus Safety, Health, and Environmental Management Association

137. University of Mississippi Medical Center

I am responding: On behalf of an organization

Name: Dr. Gene L. Bidwell

Name of Organization: University of Mississippi Medical Center

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: UMMC-Comment_Biosafety-NIH.docx

THE UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
EDUCATION · RESEARCH · HEALTHCARE

Office of Associate Vice Chancellor for Research
2500 North State Street, Jackson MS 39216
Phone: 601-815-2681

Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Re: NOT-OD-26-112

To Whom It May Concern,

The University of Mississippi Medical Center (UMMC) supports NIH's goal of providing consistent biosafety oversight proportionate to research risk. The proposed policy, however, contains conflicting instructions about the research it covers, the approvals needed to begin work, and the incidents that must be reported. Institutions need a single, consistent answer to each of these questions before the policy becomes effective. We request amendments to the provisions identified below, followed by a phased implementation period that permits institutions to revise their procedures and systems.

Conflicting requirements that need amendment

1. Section II scope and Section III incident reporting

Section II defines covered research through two cumulative requirements: a known or potential risk to human health AND involvement of at least one of four enumerated categories. Both conditions must be satisfied. Neither potential human-health risk alone nor the presence of an enumerated material alone establishes coverage. NIH funding and a laboratory's BSL/ABSL designation do not independently satisfy this definition.

Section III-B does not consistently preserve that boundary. Its general incident-review provision applies to research subject to the Policy, and its animal-incident bullet repeats that qualification. The adjacent first-aid bullet instead refers to any incident at BSL-1/ABSL-1 or BSL-2/ABSL-2 when first aid is administered without requiring that the research satisfy Section II. Read literally, the unqualified first-aid provision would require IBC review and public reporting of a minor injury even when the study involves none of Section II's four categories. The injury could demonstrate human-health risk, but it would not establish involvement of an enumerated material. The incident provision therefore states a broader trigger than the scope provision. Other language limiting review to covered research does not remove the need to reconcile these instructions.

Requested correction: State expressly that the incident review, reporting, and publication requirements apply only when the underlying research satisfies BOTH Section II conditions. Apply that qualification consistently throughout Section III and the required templates.

2. Other federal agency oversight and mandatory IBC approval

Section II says covered research that is also under another federal agency's regulation or purview may proceed under that agency's oversight once its approvals or clearances have been obtained. Section III-C, however, prohibits covered research from proceeding without IBC or delegated approval, and Section IV-2 specifically prohibits initiation of clinical research until IBC and other applicable approvals are obtained.

For a clinical study authorized by FDA, Section II provides apparent permission to proceed while Sections III-C and IV-2 require an additional approval. The draft does not state whether the other-agency provision is an exception to the later requirements or merely an additional condition.

Requested correction: State whether other-agency authorization supplements or substitutes for NIH and IBC oversight. If it supplements that oversight, revise Section II to require all applicable approvals before initiation. If it substitutes, identify the requirements displaced and add the corresponding exception to Sections III and IV.

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3. The laboratory setting definition and covered clinical research

Section II confines the policy to biomedical research in laboratory settings and defines laboratory research as research conducted within BSL/ABSL 1–4 containment facilities. Section IV-2 nevertheless requires IBC review of specified clinical administrations, and Section V-E expressly recognizes that clinical administration commonly occurs in settings that do not conform to laboratory BSLs. The definition therefore does not consistently encompass a setting that the operative provisions expressly regulate.

Requested correction: Revise Section II to include the clinical activities and settings NIH intends to cover, including those outside designated BSL/ABSL facilities. Specify how incident-reporting categories organized around BSL/ABSL levels apply in those clinical settings.

4. Overlapping NIH reportable and local only incident categories

Section III-B requires NIH reporting of BSL-2/ABSL-2 exposures that require agent-specific treatment beyond basic first aid. Its subsequent category of incidents that do not require NIH reporting includes any animal incident during covered research at BSL-1/ABSL-1 or BSL-2/ABSL-2, with bites and scratches among the examples.

An ABSL-2 animal bite involving a deliberately studied agent and requiring agent-specific treatment beyond first aid satisfies both descriptions. One provision requires NIH reporting; the other places the same event in a category described as not requiring it. This conflict persists even when the research clearly satisfies Section II.

Requested correction: Harmonize the reporting requirements and remove the reporting requirement for minor injuries that do not represent a contagious infection risk. Apply the same precedence rule to the template so an institution can assign an incident to one reporting pathway consistently.

5. The incident template requires submission of reports the policy excludes

Section III-B requires the incident template for public reports, including reports that do not require submission to NIH. Yet the Draft NIH Incident Reporting Template, page 1, states: “Completed reports must be sent to NIH.” Page 2 of the template itself recognizes that only some reports require NIH submission. An institution completing a local-only report therefore receives incompatible submission instructions.

Requested correction: Replace the unconditional instruction with a direction to submit reports to NIH only when Section III-B requires submission. Add a field distinguishing NIH-reportable incidents from those requiring institutional review and public posting only. Make that distinction consistent across the policy, instructions, and report fields.

<u>Implementation burden and compliance guidance</u>

6. Transition for existing research

Section II would apply the policy to ongoing NIH-supported work and otherwise covered non-NIH-funded work at NIH-funded institutions six months after publication. Section III-A also requires an NIH-approved Biosafety Assurance before covered research may proceed. Institutions will need to identify newly covered

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2500 North State Street, Jackson MS 39216
Phone: 601-815-2681

projects, obtain reviews, revise electronic records and reporting routes, and train investigators and reviewers. NIH's own Assurance-review capacity will affect whether institutions can meet the deadline.

Please establish a phased transition for ongoing work, explain how existing IBC approvals will carry forward, and provide a transition mechanism for institutions with timely submitted Assurances awaiting NIH action. The implementation period should begin only after the final templates and operational guidance are available. NIH should assess the workload created by institution-wide coverage regardless of a project's funding source and consider limiting the requirements only to NIH-funded research.

7. Proportionate review and documentation

Section III-B calls for a de novo registration and review at intervals no longer than three years. We suggest a process for a focused renewal for unchanged protocols, with a current assessment of materials, procedures, containment, personnel, and relevant incidents. Require a complete resubmission only when changes warrant it. This would preserve reassessment without routinely recreating information already held by the institution.

We support the delegated-review mechanism in Section IV-3. NIH should provide criteria for minor amendments and standardized review of recurring low-risk activities. The required minutes template already allows delegated approvals to be recorded as a list; the final policy should clearly preserve that option. Equivalent institutional minutes formats should also be acceptable when they capture the required decisions and rationale.

Sections III-A and III-C assign training duties to institutions and PIs, and Section III-B requires periodic review of approved research. Please identify the minimum training content, acceptable documentation, and expectations for periodic review. Existing training and inspection programs should satisfy these duties when they address the applicable requirements. NIH should provide example IBC application questions addressing the biohazard, experimental procedures, and any genetic modifications. The amount of detail required should reflect the risks and complexity of the proposed work.

8. Incident workflows records and public disclosure

IBC review, NIH notification, and public posting create distinct institutional tasks. Please allow initial incident reporting through existing safety or occupational-health channels, with timely referral for required IBC review and NIH notification. Identify which incident reviews may be delegated and how those reviews must be recorded. For minor administrative lapses and low-risk incidents, NIH should adopt reporting and documentation requirements proportionate to the event's consequences and corrective action.

Section III-A requires at least five years of public access to minutes and incident reports, while some underlying award records must be retained longer. Please provide a retention schedule that addresses public copies, underlying records, records linked to multiple awards, and research without a federal award. Institutions need those specifications to configure and validate their record systems.

The expanded public-posting duties also require staff time for preparation, review, and redaction. Please identify the information that must appear publicly and permit a separate complete institutional record. Redaction guidance should address personnel privacy and the security implications of disclosing animal facilities, operational details, and related information across multiple public documents. The final guidance should explain how to report medical response and corrective action without identifying affected personnel.

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9. Definitions needed to apply the requirements consistently

Two provisions in Section IV-2 need operational definitions. Primary cells that may contain adventitious agents could encompass a very broad range of specimens without a criterion for credible contamination risk. NIH should specify how cell source, screening, and planned manipulations determine the review requirement. Similarly, the examples of higher-risk clinical manipulations do not establish a decision rule. NIH should identify the relevant product and procedure characteristics and provide examples on both sides of the threshold.

We disagree with defining transient expression from non-integrating, non-replicating mRNA as genetic modification solely because the mRNA can be translated. Section II's definition conflates introduction of a template for temporary protein production with alteration of the recipient's genome. NIH should distinguish these processes explicitly and revise the definition so that non-integrating, non-replicating mRNA that produces transient protein expression without inducing stable genomic changes is not classified as genetic modification merely because it is translated.

This distinction should not exclude mRNA used to induce stable genomic changes, such as delivery of a gene-editing enzyme. Nor would it prevent biosafety oversight when the research otherwise satisfies both Section II conditions, for example through expression of a covered toxin. Risks associated with an encoded product, its delivery, or experimental exposure should be assessed on their own merits.

10. Implementation at rural and community research sites

Our institution serves a largely rural state. NIH should assess whether the proposed implementation requirements could reduce rural access to covered research. Where covered studies are conducted through geographically dispersed hospitals and clinics, uncertainty about clinical settings and oversight responsibilities could encourage institutions to concentrate those studies at a central academic campus. That could increase travel burdens for rural participants. NIH should clarify how covered research can be conducted safely in community settings without unnecessary duplication of oversight.

The final policy should expressly describe how a central or externally administered IBC may oversee covered work at satellite and affiliated sites. It should distinguish a participating location from a separate institution and specify who must hold a Biosafety Assurance, review incidents, maintain records, and post reports. Shared training, records, and oversight should be permitted when they satisfy the applicable requirements. Assessment of each site should reflect its actual activities and biosafety risks.

A smaller research partner conducting relatively few covered studies could face substantial administrative work per study. The proposed duties do not expressly require every rural clinic to establish its own IBC or obtain a separate Assurance, but unclear allocation of responsibilities could lead institutions to duplicate functions unnecessarily. NIH should provide a framework for shared oversight and reliance arrangements that preserves institutional accountability while making community participation feasible.

The six-month transition also needs to account for coordination across multiple sites and organizations. NIH should provide standardized training and reporting resources and phase in requirements for existing networks after those resources are available. The transition should allow institutions to establish shared procedures and obtain required approvals without unnecessarily interrupting covered research in rural communities.

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We request that NIH reconcile the conflicting instructions in the policy and templates before finalization, then provide the definitions and transition arrangements necessary for consistent implementation. Institutions should be able to determine what research is covered, which approvals are required, and where an incident must be reported by applying one coherent set of requirements.

Sincerely,



Gene L. Bidwell, III, Ph.D.
Associate Vice Chancellor for Research
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216

138. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Comments on Section IIIB:
- IIIB: “Any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approvals…” Question: Does NIH really want a report sent if a PI is late to renew their IBC registration? How late is reportable?
- IIIB: Question: If a researcher is collecting blood from a participant and a needlestick happens and the researcher seeks medical attention for the BBP risk, including HIV prophylaxis, would this have to be reported to NIH and publicly posted on the institution’s website?
- IIIB: Comment: I question if mandatory public posting of incidents provides meaningful transparency benefits beyond existing reporting and disclosure mechanisms. I am also concerned that public posting requirements could lead to less reporting of incidents or seeking guidance from biosafety professionals. Principal investigators may become more hesitant to provide research and training opportunities to students, trainees, and less experienced laboratory personnel if publicly posted incidents are perceived as carrying reputational consequences, particularly given the increased likelihood of errors occurring during training and skill development.

6. Other feedback relevant to this resource: '- Section II: Question: Will a timeline and transition period be published? “6 months from publication of final Policy” would be difficult deadline to meeting as electronic protocol applications, training, posting, IBC charters, policies, etc. would have to be changed.

- Section IIIA: Question: Will a template “Assurance” be provided to institutions?

139. George Mason University

I am responding: On behalf of an organization

Name: Ericka Pearce, IBC Contact and Biosafety Officer on behalf of the George Mason University IBC

Name of Organization: George Mason University

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Definition and Oversight of Toxins

The George Mason University IBC supports NIH's intent to ensure appropriate oversight of biologically derived toxin research. However, the proposed definition of a toxin as "a protein or peptide produced by living organisms that causes harm in humans" is overly broad and may result in inconsistent interpretation and implementation across institutions.

As written, the definition could encompass a wide range of materials with different hazard profiles, including venoms, endotoxins, algal and fungal toxins, commercially available purified toxins, and non-Select Agent toxins below Federal Select Agent Program permissible thresholds.

Operational Impact: Without clearer, risk-based applicability criteria, institutions may reach different conclusions regarding which toxin research activities require IBC review, increasing administrative burden while providing limited additional biosafety or biosecurity benefit.

Recommendation: NIH should consider retaining the existing toxin oversight scope established under the NIH Guidelines until more specific risk-based applicability criteria can be developed. NIH Guidelines Section III-B and Appendix F-I already provide a well-established trigger for NIH/IBC review of experiments for genes encoding toxin molecules with LD50 thresholds. Toxin research is also governed through multiple complementary oversight mechanisms, including Federal Select Agent Program regulations and toxin due diligence programs, as well institutional laboratory-specific risk assessments in accordance with the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

140. George Mason University

I am responding: On behalf of an organization

Name: Ericka Pearce, IBC Contact and Biosafety Officer on behalf of the George Mason University IBC

Name of Organization: George Mason University

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): George Mason University's Institutional Biosafety Committee supports modernization of the NIH biosafety framework and encourages a final policy that is clear, risk-based, and scalable across institutions with diverse research portfolios. As a growing research university with a strong commitment to student engagement in research and education, our priority is to support the safe, ethical, and compliant conduct of biological research through a framework that is both effective and practical to implement. We encourage NIH to align requirements with demonstrated biosafety and biosecurity risks, preserve institutional flexibility, and provide clear implementation guidance, examples, and transition provisions. We also encourage NIH to consider the cumulative impact of concurrent federal research oversight initiatives and, where possible, harmonize requirements, reporting mechanisms, and implementation timelines. The final policy should strengthen biosafety practices while minimizing duplicative or low-value administrative requirements that could disproportionately impact institutions of varied sizes, missions, and research capacities or divert limited biosafety resources from activities presenting the greatest potential risk.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

141. George Mason University

I am responding: On behalf of an organization

Name: Ericka Pearce, IBC Contact and Biosafety Officer on behalf of the George Mason University IBC

Name of Organization: George Mason University

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Scope of Genetically Modified Organisms

The George Mason University IBC supports NIH's goal of ensuring appropriate oversight of emerging biotechnology and genetically modified organisms. However, the proposed scope provision covering "cells, viruses, or organisms, other than plants, that have been genetically modified" may unintentionally expand IBC oversight to a broad range of routine, low-risk research activities.

As written, the definition of genetic modification includes nucleic acid molecules that "can be transcribed or translated," potentially encompassing common molecular biology tools and models such as expression vectors, reporter constructs, commercially available modified cell lines, transgenic animals, and CRISPR-edited cells with well-characterized risk profiles.

This concern was identified immediately by a Principal Investigator and IBC member during our initial committee review of the draft policy. Investigators routinely evaluate the risks associated with genetic modifications as part of study design and required IBC submissions. The concern is not whether genetically modified materials warrant oversight, but whether oversight should be triggered by the presence of a genetic modification alone, regardless of its impact on biosafety or biosecurity risk.

Operational Impact: A broad interpretation could substantially increase the number of protocols requiring IBC review, lengthen review timelines, and divert limited IBC and biosafety resources from higher-risk activities, including new high-consequence life sciences research oversight requirements by our Institutional Review Entity.

Recommendation: NIH should clarify whether oversight is intended to be triggered by the presence of a genetic modification or by the biosafety and biosecurity risks associated with that modification. We encourage NIH to adopt a risk-based approach and consider exclusions for common, low-risk molecular biology tools, established research models, and commercially available reagents. This would better align

oversight with actual risk and help ensure limited IBC resources remain focused on activities presenting the greatest potential concern.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

142. George Mason University

I am responding: On behalf of an organization

Name: Ericka Pearce, IBC Contact and Biosafety Officer on behalf of the George Mason University IBC

Name of Organization: George Mason University

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Broad Reporting Triggers and Undefined Terms

The George Mason University IBC supports NIH's goal of improving transparency and consistency in incident reporting. However, several reporting triggers rely on broad, undefined terms such as "any incident," "any compliance violation at any biosafety level," "potential exposure," and "potential laboratory-acquired infection." Without clearer definitions or regulatory triggers, institutions may interpret these terms differently, resulting in inconsistent reporting practices.

Several reporting categories also appear to overlap. For example, "any incident" at higher containment levels may be broader than the examples that follow; minor spills may be excluded in one section but potentially captured elsewhere; and animal bites, scratches, or compliance violations may be reportable even when no biohazard exposure or meaningful biosafety risk exists. Terms such as "basic first aid" and "agent-specific treatment" are also undefined.

The draft further creates uncertainty regarding the relationship between occupational health responsibilities and Principal Investigator (PI) responsibilities. While PIs are responsible for communicating required occupational health and exposure-response procedures, the policy does not clearly identify when an Occupational Health Surveillance Program is required, who determines that need, or who develops the procedures.

Operational Impact: Broad and overlapping reporting requirements may encourage reporting of low-risk events, near misses, and administrative issues, creating substantial burden for investigators, biosafety personnel, occupational health programs, IBCs, and recipients of these reports at the NIH Office of Science Policy (OSP). As one example, a laboratory injury at our institution that was currently non-reportable to NIH OSP required 6-8 hours of biosafety staff time, follow-up regarding corrective actions, as well as occupational healthcare practitioner and IBC review before closure. Expanding reporting to broadly defined "potential" events could significantly increase this workload without a corresponding biosafety or biosecurity benefit. Over-reporting may also reduce the effectiveness of reporting systems by making it more difficult to identify incidents that present significant biosafety or public health concerns.

Recommendation: NIH should provide clearer definitions, objective reporting thresholds, and better examples of reportable events. We encourage NIH to retain or incorporate more objective, risk-based terminology, such as "overt exposure," clarify occupational health responsibilities and triggers, and focus mandatory reporting on incidents that present meaningful biosafety, biosecurity, or public health concerns. This would promote more consistent implementation while ensuring limited oversight resources remain focused on the highest risk events.

143. Vicente Zuno Fernández

I am responding: On behalf of myself

Name: Vicente Zuno Fernández

Name of Organization: Houston Methodist Research Institute

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/12/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): HMRI is a multidisciplinary biomedical research institution emphasizing the translation of laboratory discoveries into clinical applications.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The expanded scope of the policy is generally appropriate and reflects the need for comprehensive, risk-based biosafety oversight. However, clearer definitions and boundaries are necessary to ensure consistent implementation without imposing unnecessary administrative burdens on low-risk research. In particular, the definition of genetic modification should distinguish permanent genetic alterations from transient nucleic acid expression, such as mRNA-based applications. Replacing the detailed NIH Guidelines with a substantially abbreviated policy, without retaining established exemptions, examples, and interpretative guidance, create uncertainty regarding which activities require oversight and at what level. NIH should clearly distinguish exempt activities, delegated reviews, and full IBC reviews, while establishing consistent, risk-based criteria that prevent oversight gaps without unnecessarily expanding regulatory requirements.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered, risk-based oversight framework is appropriate, provided that responsibilities between federal agencies and local institutions are clearly defined. Local IBCs and BSOs should retain authority to assess and manage routine research activities based on institution-specific risks, while federal oversight should focus on higher-risk research, significant incidents, and activities requiring specialized review. The policy should establish clear criteria for escalating oversight, preserve institutional flexibility, and avoid duplicative administrative requirements. Additionally, federal expectations should be proportional to the actual biological risks involved rather than imposing uniform requirements across all research activities.

3. Continued utility of Risk Groups: Risk Groups (RGs) remain valuable as a baseline for biological risk assessment and should be retained within the proposed policy. However, RG classifications alone are insufficient to determine appropriate containment, particularly when organisms undergo genetic modifications that may alter pathogenicity, transmissibility, host range, or other biological characteristics. Biosafety Levels (BSLs), as described in the BMBL, provide a more comprehensive, activity-based framework that considers agent characteristics, experimental procedures, exposure potential, and available safeguards. NIH should preserve the distinction between RG classifications and

BSL containment requirements while emphasizing comprehensive, risk-based assessments conducted at the institutional level. This approach would provide flexibility without compromising biosafety or introducing unnecessary regulatory complexity.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary compliance by providing accessible guidance, standardized risk assessment tools, training resources, and model institutional policies. Voluntary adoption should remain flexible and risk-based, particularly for smaller institutions with limited biosafety resources. Clear distinctions between mandatory requirements and recommended practices would promote broader participation without creating unnecessary administrative or financial burdens.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed templates may improve consistency and transparency but should remain flexible and proportional to risk. Incident reporting should clearly distinguish events requiring immediate notification from those appropriate for routine institutional documentation. Reporting requirements should avoid duplicating information already captured through institutional incident management systems. Similarly, IBC meeting minutes should document substantive discussions and decisions without imposing excessive administrative burdens. Public disclosure requirements should adequately protect confidential research information, personnel privacy, and institutional security.

6. Other feedback relevant to this resource: NIH should provide comprehensive implementation guidance, including standardized risk assessment tools, clearer definitions, practical examples, and decision-making frameworks for determining oversight requirements. Additional guidance is particularly needed regarding BSO qualifications and responsibilities, IBC review thresholds, incident reporting criteria, and the distinction between mandatory requirements and recommended practices. Retaining relevant examples and interpretations from the existing NIH Guidelines would promote consistency and reduce uncertainty. NIH should also provide adequate transition periods, training resources, and technical assistance to support implementation without imposing unnecessary administrative burdens.

Uploaded File: Comments-for-Submission-Draft-NIH-Biosafety-Policy-10.7.2026.pdf

Description: Vicente Zuno - Comments for Submission - Draft NIH Biosafety Policy

October 7, 2026

Dear NIH OSP,

I appreciate the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. I submit these comments in my individual capacity as a biosafety professional with experience supporting IBC oversight, conducting biological risk assessments, investigating laboratory incidents, inspecting containment laboratories, and advising investigators.

I support NIH's effort to modernize biosafety oversight, expand the framework beyond recombinant and synthetic nucleic acid research, and establish a more risk-based system. However, several areas would benefit from clarification or additional guidance:

1. Qualifications and Competency Requirements for Biological Safety Officers

I strongly recommend that NIH establish minimum competency expectations for Biological Safety Officers (BSOs).

The draft assigns BSOs significant technical responsibilities, including inspection of containment facilities and equipment, assessment of compliance, investigation of incidents, identification of violations, and technical advice to investigators and the IBC. These functions require specialized knowledge and professional judgment, yet the draft specifies no minimum education, training, experience, or competency requirements.

NIH should establish a competency-based framework addressing areas such as biological risk assessment, containment, laboratory practices, incident investigation, applicable standards, and IBC oversight. Institutions could retain flexibility in demonstrating competency through education, experience, training, professional credentials, or a combination thereof.

2. Assignment of BSO Responsibilities to an "Other Official"

I am particularly concerned by the provision stating that, if an institution does not designate a BSO, another official must assume the BSO's responsibilities.

These responsibilities remain technical regardless of the title of the individual performing them. Incident investigation, containment assessment, laboratory inspection, and technical recommendations to an IBC require appropriate expertise.

NIH should remove this provision or clarify that any individual performing BSO functions must meet equivalent competency expectations. Otherwise, the Policy risks creating significant variability in the qualifications of those responsible for institutional biosafety oversight.

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

3. Circumstances Requiring Appointment of a BSO

NIH should reconsider limiting mandatory BSO appointment primarily to institutions conducting BSL-3/BSL-4 research or research involving GDMOs.

The proposed Policy expands biosafety oversight to wild-type biological agents, toxins, primary cells, and other biohazards. An institution could maintain a substantial BSL-2 program involving human pathogens while having significant responsibilities under the Policy without being required to designate a BSO.

NIH should either broaden the circumstances requiring a qualified BSO or provide criteria based on the size, complexity, and risk profile of an institution's research program.

4. Qualifications and Procedures for Delegated IBC Review

I support delegated review for appropriate lower-risk research, but additional guidance is needed regarding who may perform these reviews and under what conditions.

NIH should clarify whether delegated reviewers must be voting IBC members, whether a BSO may independently conduct delegated review, minimum reviewer competency, conflict-of-interest requirements, documentation expectations, and circumstances requiring elevation to full committee review.

A model delegated-review procedure would improve consistency among institutions while preserving institutional discretion to apply more restrictive review standards.

5. Activities Outside the Policy and Removal of Existing Exemptions

The draft identifies certain activities as outside the Policy but does not provide an exemption structure comparable to the current NIH Guidelines.

Clear boundaries are essential to prevent unnecessary administrative burden and inconsistent interpretation. NIH should develop a decision framework distinguishing:

- Activities outside the Policy;
- Activities not requiring IBC review;
- Activities eligible for delegated review;
- Activities requiring full IBC review; and
- Activities requiring both NIH and IBC review.

Representative examples of commonly conducted biomedical research would be particularly useful.

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

6. Incident-Reporting Thresholds and Public Posting

Additional guidance is needed to distinguish incidents requiring NIH reporting from those that may be managed institutionally.

Terms such as “minor spill,” “low-risk agent,” “breach of containment,” and “significant risk to human health” may be interpreted differently among institutions. NIH should provide a decision tree and representative examples identifying events requiring immediate NIH reporting, routine reporting, internal review only, or no formal reporting.

NIH should also establish clear standards for redacting publicly posted incident reports to protect personal and medical information, confidential research information, security-sensitive facility information, and ongoing investigations.

7. Relationship Between Risk Groups and Biosafety Levels

I encourage NIH to retain Risk Groups as one component of biological risk assessment while providing clearer guidance regarding their appropriate use.

Risk Group and Biosafety Level are not interchangeable. Risk Group describes characteristics of a biological agent, whereas containment level should result from a protocol-specific risk assessment considering the agent, procedures, concentration, volume, exposure routes, aerosol generation, animal models, genetic modifications, and other experimental factors.

Because confusion between RG classification and BSL assignment remains common, the new Policy provides an opportunity to clearly distinguish these concepts and reinforce protocol-specific risk assessment.

8. Implementation Guidance and Transition Period

The proposed Policy represents a substantial change in institutional biosafety oversight. Institutions may need to revise committee jurisdiction, procedures, electronic systems, delegated-review processes, incident-reporting procedures, institutional websites, training, and existing research registrations.

NIH should make implementation resources available well before the effective date. Particularly useful resources would include:

- A model Institutional Biosafety Assurance;
- A model IBC charter;
- A biosafety registration template;
- A delegated-review procedure;

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

- Scope and review-category decision trees;
- Incident-reporting guidance;
- BSO competency guidance;
- IBC and reviewer training materials;
- Public disclosure and redaction guidance; and
- Transition guidance for existing research.

These resources would be especially valuable to smaller institutions without dedicated biosafety or regulatory personnel.

9. Definition of Genetic Modification

I recommend that NIH revise or clarify the proposed definition of "genetic modification."

The draft includes introduction of nucleic acid molecules that "can be transcribed or translated." Transcription or translation alone, however, does not necessarily result in a stable or heritable genetic alteration.

For example, transient introduction of mRNA can result in translation of an encoded protein without altering the cellular genome. Likewise, non-integrating nucleic acid constructs may produce transient expression without creating a stable genetic modification.

NIH should clarify whether transient nucleic acid expression is intentionally being classified as "genetic modification." If such research is intended to remain within the Policy, terminology should distinguish transient nucleic acid expression from stable genomic modification. If not, the definition should be revised accordingly.

Clear terminology is essential because this definition directly affects whether research falls within the Policy and what oversight is required.

10. Clarity and Proportionality in Compliance and Enforcement

The proposed Policy includes potentially significant consequences for noncompliance, including additional terms and conditions, termination, and effects on future NIH funding decisions. Given the breadth of the Policy and its transition from detailed Guidelines to a more streamlined framework, NIH should clearly explain how compliance and enforcement determinations will be made.

NIH should clarify:

- How inadvertent or good-faith interpretive errors will be distinguished from serious, repeated, reckless, or intentional noncompliance;

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

- Whether institutions will ordinarily have an opportunity to implement corrective actions before severe enforcement measures;
- What factors will determine the severity of an enforcement response;
- How actual or potential biosafety risk will influence enforcement; and
- How NIH will address provisions reasonably subject to more than one interpretation.

A risk-based biosafety policy should be accompanied by a risk-based and proportionate compliance framework. Clear enforcement principles would encourage self-identification and correction of problems while reducing the risk of disproportionate consequences for ambiguous or low-risk compliance issues.

Conclusion

The proposed NIH Biosafety Policy is an important opportunity to modernize biological research oversight, but its success will depend on clear scientific terminology, qualified biosafety professionals, and sufficiently detailed implementation and enforcement guidance.

As NIH expands institutional responsibilities, it should establish appropriate competency expectations for BSOs and others performing BSO functions. Key definitions, including "genetic modification," should also be scientifically precise and avoid unintentionally capturing activities that do not constitute stable genetic alteration.

Finally, simplification of the current NIH Guidelines should not eliminate the examples and distinctions institutions need to understand their obligations. Where noncompliance may carry significant funding consequences, institutions should be able to determine prospectively what the Policy requires. A risk-based biosafety policy should therefore be supported by clear implementation guidance and a proportionate, risk-based compliance framework.

Thank you for considering these comments.



Vicente Zuno, RBP (ABSA), CPH (NBPHE) – Provisional

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

144. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: IBC Coordinator

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The level of detail requested per registration in the Draft Meeting Minutes Template is so onerous that it seems it would be easier to just attach copies of each entire registration. For instance, if no training concerns were discussed for a particular registration, why must every training for every listed personnel be included in the minutes? This, among other fields, will just become a copy-paste of 'Basic Biosafety, Bloodborne Pathogens, IBC Training...' etc. Likewise, shouldn't the Project Overview just be the Lay Summary? If a single registration utilizes 9 agents, are we expected to list every agent and describe each agent's characteristic, source, modification, experimental manipulation, etc.? Again, it would then just be easier to attach a PDF of the entire registration and write 'See attached' in the Template.

If required to use the provided Template, the minutes will be one long continuous table of information. Posting a PDF version of minutes to a public-facing website requires adherence to ADA requirements for the document. Making tables that cross multiple pages ADA compliant is a nightmare, adding significant administrative burden to the requirement of posting the minutes immediately after they are approved.

6. Other feedback relevant to this resource: N/A

145. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cardiovascular diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: 1) Double-blind review: Score science anonymized first, then reveal investigator/environment for a feasibility check only.
2) Panel rosters: Release on meeting day, not a month before.
3) Standing reviewers: Limit rather than eliminate. Shorter terms, mandatory rotation, and a mix of standing and ad hoc reviewers to keep scoring calibrated.
4) Accountability: Let applicants flag factual errors in critiques, have SROs rate review quality, and stop inviting poor reviewers.

146. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Having the incident reports be posted publicly is a deterrent for reporting; recommend instead that the institution be required to post aggregate annual reports that do not name individual investigators, with more strategic root cause analyses and mitigations. Also unclear how the institution is meant to do root cause analysis; for example, NASA defines "root cause analysis" for mishap investigations as organizational by definition. In other words, a "root cause" is always organizational. Done badly, this sort of analysis could always default to blaming upper management for being "negligent" or "underfunding" an area, or blaming the institution for "having a toxic culture". Therefore it seems more useful to have the institution do analyses across multiple incidents to come up with a strategic organizational response and set of remedies.

6. Other feedback relevant to this resource: N/A

147. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Other

Role: Other

Role - Other: Biorisk Management

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See response to #5 below as it covers appropriateness of the new policy and oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: There are major biosecurity implications with the details required in the incident reporting and meeting minutes templates. Requiring PI names along with their research and agents can make them an easy target for bad actors, specifically if working with biological select agents and toxins. Requiring any names on the minutes puts these individuals at risk for harassment and targeting, particularly government employees. Also, requiring the institution name, location, biosafety level, pathogen, and risk assessment provides bad actors with readily available information that could have dual use ramifications which flies in the face of biosecurity completely. At what cost are we willing to trade personnel and institution security to appease certain populations who do not understand the vulnerable position this presents for our institutions and our researchers? I cannot imagine anyone in the intelligence community, WMD coordinators, or security professionals are ok with this information being readily shared on a public facing website.

6. Other feedback relevant to this resource: N/A

148. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Healthcare Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As written, "may be contaminated" could be interpreted to include virtually any primary human or animal cells (including any research involving NHP cells or tissues) for which the infectious-agent status of the source has not been comprehensively established.

NIH should define "adventitious agent," establish a risk-based threshold for determining when contamination is reasonably anticipated, and clarify whether donor screening, testing, source information, or other documentation can establish that primary cells do not fall within this category. The Policy should also clarify its application to commercially obtained cells, repository specimens, patient-derived cells, and primary animal cells and provide examples of included and excluded materials. A merely theoretical possibility of contamination should not independently trigger IBC oversight; the definition should be tied to a known or reasonably anticipated potential hazard to human health. Clear criteria are necessary to avoid additional administrative burden by unnecessarily expanding IBC oversight beyond research presenting a meaningful biosafety risk

The Policy does not provide sufficiently objective criteria for determining when a cell line qualifies as well-characterized, creating the potential for inconsistent interpretations among investigators, biosafety professionals, and IBCs. NIH should specify what level of information regarding identity, provenance, biological characteristics, and adventitious-agent testing is necessary; whether established commercially available or widely used cell lines may be presumed to satisfy the definition; and how primary, immortalized, genetically modified, and patient-derived cells should be treated. NIH should also provide examples of included and excluded cell lines. Because this determination may affect the scope and level of institutional oversight, a clear, risk-based definition is necessary to ensure consistent implementation and avoid additional administrative burden by unnecessary review of research that does not present a meaningful biosafety risk.

IBC review is appropriate for the review of research involving prions or biospecimens identified to be from a person or animal known to have a prion-based disease. However, the term self-aggregating is not

sufficiently defined to permit institutions or investigators to determine consistently if every protein that happens to aggregate or contributes to an aggregation-associated human disease, such as ALS, is also covered.

Protein aggregation alone does not necessarily establish a meaningful biosafety hazard. NIH should clarify whether "other self-aggregating proteins" is intended to encompass proteins with prion-like, seeding, propagation, transmissibility, pathogenic, or other specified hazard characteristics rather than any protein capable of aggregation. The definition should identify objective criteria and provide examples of both covered and excluded materials.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: It is recommended that NIH maintain the previously established categories of exempt research. NIH describes the purpose of the modernization as expanding oversight to biohazards while "removing red tape for low-risk research" and specifically asks commenters whether the proposed tiered oversight is appropriately calibrated to risk and administrative burden.

Exempt from IBC oversight is not synonymous with exempt from safe laboratory practice. Rather, it represents a determination that the incremental safety benefit of mandatory IBC oversight does not justify the administrative burden for a defined class of low-risk research. Currently exempt research was previously determined by NIH, following notice and opportunity for public comment, not to present a significant risk to health or the environment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It is recommended that NIH revise the approach to public posting of incidents so that detailed incident reports are submitted to NIH but are not routinely required to be posted publicly in their entirety. Alternatively, NIH could provide a template for public posting of standardized, de-identified high level summary information of incidents that might include root-cause categories and corrective actions. NIH could separately require disclosure of additional information when a particular incident presents a compelling public health or safety interest.

This approach balances transparency objectives with the equally important need to preserve a just, non-punitive reporting culture in which researchers and staff are encouraged to report incidents, near misses, and potential safety concerns promptly and completely. It also provides protections for researchers that are increasingly threatened or harassed due to the tools or subject matter of their research. Importantly, NIH would receive the information necessary to evaluate significant incidents, institutional responses, and compliance. The distinction would therefore be between information necessary for regulatory oversight and information necessary for public transparency, rather than assuming that the same level of detail is needed for both purposes.

6. Other feedback relevant to this resource: A six-month implementation period is insufficient given the breadth, complexity and institutional impact. Revising electronic systems to accommodate the new regulations is a significant challenge that will likely prevent many institutions' ability to meet this timeline. Additionally, updating policies and procedures and ensuring that researchers have the training

they need to understand the new requirements, including newly covered areas of research, will require additional time. The time required to identify newly covered research is one reason why it is critical for entities to be held to realistic and achievable implementation timelines.

NIH should provide a detailed description of the required elements of an institutional assurance and publish accompanying implementation guidance before policy adoption, including model assurance language, implementation templates, and sufficient lead time for institutions to develop. Administrative burden should be kept in mind in considering required elements.

The incorporation of delegated review has the potential to decrease regulatory burden and expedite review of low-risk research. However, the draft policy is unclear in what may qualify for delegated review.

- It appears that it is the intent that initial protocols only containing work identified as eligible for delegated review under Section IV-3. Clarified wording is recommended "for minor amendments to previously approved submissions or for initial research protocols"
- There are inconsistencies between the descriptions of research that require committee review (Section IV-2) and research that may be eligible for delegated review (Section IV-3). A potential clarification is to state that "Where research is described by both Section IV-2 and Section IV-3, research meeting all applicable criteria specified in Section IV-3 may undergo delegated review unless another characteristic of the research independently requires review under Section IV-1 or IV-2. A delegated reviewer may refer any submission to the full IBC when warranted based on the risk assessment."

Section IV-2 outlines the only clinical research provision and specifically identifies IBC review for biohazards that shed, replicate, integrate, require higher-risk manipulation, or involve RG2 or higher wild-type agents. There is no discussion of other genetically modified agents being used in clinical research, such as plasmids or RNA, and no discussion of exemptions. Given the federal administration's efforts to streamline and accelerate the development of innovative therapies through clinical trials, additional administrative burden should not be introduced by expanding IBC oversight in the clinical research arena.

The Policy should also exempt any covered clinical research studies from mandatory three-year de novo IBC review or permit an administrative continuation process confirming that no material changes affecting biosafety have occurred. Full IBC review should be required only for clinical research presenting local biosafety risk, where there may be questions regarding product handling and possible shedding. This approach would maintain appropriate biosafety oversight while reducing unnecessary regulatory burden

149. Amy Wilkerson

I am responding: On behalf of myself

Name: Amy Wilkerson

Name of Organization: The Rockefeller University

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): broadly biomedical: Neuroscience, structural biology, immunology, virology, cancer biology, genetics, microbiology, mechanisms of human disease, organismal biology and evolution, computational biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Implementation period: The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research. Please allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.
Public disclosure and record retention: The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure. Please consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

150. Austin

I am responding: On behalf of myself

Name: Austin

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Research Compliance Officer

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: • The definition of "biohazard" will significantly affect program scope and administrative burden. NIH should provide additional examples and decision tools to promote consistent interpretation of covered biohazardous materials across institutions.
• How can institutions ensure consistent categorization of research activities when multiple biosafety risk factors exist? Many projects do not fit neatly into a single category. NIH should consider developing standardized case studies and decision-support tools to improve consistency in risk determinations across institutions.

Policy reference Section I
The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.
Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

Policy reference Section II
Coverage and decision rules
The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.
Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or

sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.
Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Assurance submission approval and renewal
A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.
Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.
Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.
Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Policy reference Section III B
Formal establishment and independent authority
The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.
Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language. The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.
As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions.

Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion

examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Committee procedures and conflicts of interest
The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.
Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

3. Continued utility of Risk Groups: Public disclosure and record retention
The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.
Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

Policy reference Section IV 1 with related petition provisions in Section III B
The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.
Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

Policy reference Sections V A through V E
The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.
Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): • What specific events require NIH notification? Institutions need greater certainty regarding reportable events and define or provide guidance on what is meant by "beyond first aid." NIH should provide clearer reporting thresholds and detailed examples of reportable and non-reportable biosafety incidents to improve consistency and reduce unnecessary reporting.

Policy reference Section III A
Accountability and minimum program support
The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.
Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.
Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.
Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Policy reference Section III C
The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.
Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.
Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data

and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident thresholds investigations and reporting
The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.
Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.
Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.
Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Policy reference Section III D
The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.
Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

6. Other feedback relevant to this resource: • How should IBCs coordinate with IACUCs when biosafety concerns arise during animal studies? NIH should provide guidance on effective coordination between IBC and IACUC oversight when animal activities involve covered biohazardous materials.
• Has NIH assessed the staffing and administrative burden associated with implementation? NIH should consider the resource implications for small and mid-sized research institutions and provide scalable implementation guidance and extended timelines. Implementation of expanded biosafety oversight responsibilities may require additional institutional resources, personnel expertise, training infrastructure, and administrative support.

• What level of review responsibility does NIH expect for subrecipients, collaborating institutions, and shared research facilities?
• Will NIH develop educational materials, case studies, and best-practice guidance that institutions can use to foster a culture of biosafety for research activities not formally subject to the policy?
• Can NIH provide voluntary training modules or awareness resources that institutions may offer to investigators whose research does not trigger regulatory review but involves biological materials or emerging technologies?
• Does NIH intend to provide scalable implementation models for institutions with varying levels of research activity, biosafety infrastructure, and staffing resources?
• Does NIH intend the Assurance to apply only to covered activities requiring biosafety oversight, or to all research involving biological materials conducted at the institution regardless of funding source or risk level?
• If an institution submits its Institutional Assurance in a timely manner but NIH review or approval extends beyond an implementation deadline, how will NIH assess institutional compliance during the interim period? Will institutions that have submitted an Assurance and implemented reasonable, good-faith oversight mechanisms be considered compliant pending NIH's final determination?
• When multiple institutions participate in a collaborative project, how should responsibility under the Assurance be allocated among participating institutions? Will NIH permit institutions to rely upon biosafety reviews performed by another assured institution, or is independent review expected at each collaborating organization?
• The draft policy references circumstances in which an Occupational Health and Safety Program may be required but does not clearly distinguish between mandatory requirements and recommended best practices. Can NIH provide specific criteria, examples, and minimum expectations to help institutions determine when an OHSP is required and what program elements must be implemented?

Implementation period
The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.
Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

Experienced program leadership and the Biological Safety Officer
The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.
Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.
Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office

director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B
Category boundaries and continuing review
Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.
Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.
Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

151. Alex M. Brown

I am responding: On behalf of myself

Name: Alex M. Brown

Name of Organization: Safety Happens, LLC

Type of Organization: Other

Type of Organization - Other: Safety/ Biosafety Consultant

Role: Other

Role - Other: Consultant/ Biosafety Officer

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Gene Therapy Manufacturing

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Clarification on the impact of contracted manufacturing, supporting clinical and preclinical research, would be helpful. It's always been ambiguous if manufacturing of viral vectors, if not included directly in the grant, is obligated to be registered and follow NIH Guidelines. Funding is not provided directly by the NIH, and clear language around what is and is not included in the scope would assist with guidance and oversight for the growing biotech manufactuing industry.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): voluntary compliance should not include mandatory reporting / posting/ disclosure of IBC minutes in order to protect private IP also utilized by manufacturing organizations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

152. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Disease Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Biosafety-Policy-Comments_13_Oct_2026.pdf

Description: NIH Biosafety Policy Comments

October 13, 2026

RE: Comments for the Draft NIH Biosafety Policy for Research Involving Biohazards (Request for Comment – NOT-OD-26-112, dated August 19, 2026)

To whom it may concern,

I am an associate professor that has been teaching and conducting research in infectious and vector borne diseases for the past 25+ years. The focus of my Ph. D. dissertation research was pathogenic bacteriology. During my career I have published multiple articles on vector-borne diseases and have presented my research and national and international meetings. I have also work closely with the regulatory and biosafety groups at my institution, so I have some experience with the current and past regulations. My comments regarding the Draft NIH Biosafety Policy for Research Involving Biohazards (the Policy) (NOT-OD-26-112, dated August 19, 2026) are below.

In general, I support the replacement of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). However, I have concerns about the Policy, including the scope, definitions, and tiers of oversight, which are described further below.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.
    a. Increased Administrative Burden: The draft policy requires Risk Group assignments for non-recombinant agents, creating additional administrative workload for institutions.
    b. The proposed Policy uses words/terms but does not define them; some of these did not have definitions in the *NIH Guidelines*, and therefore this is a good opportunity to define these listed below:
        i. Organism
        ii. Transgenic
        iii. Adventitious agent
        iv. Virus as a “living organism”

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).

a. **General Definitions: *Toxin***
    i. The definition of toxin is poor. Clearly state that “living organism” does not include viruses.
    ii. Alternatively, adopt a clearer definition. For example, ISO35001 uses “substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants. This includes substances and materials, natural or as a result of biotechnology, that may contain toxins, any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance.”
b. **Section IV-1 (Research that Requires NIH and IBC Approval Before Initiation): *Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL.***
    i. For researchers who identify new biological agents, there is no path to work with these agents. Once identified as an “emerging agent” with no risk group or biosafety level recommended in the BMBL, the research must be approved by NIH. However, without the ability to work on the agent, the researcher cannot generate the data required for NIH to conduct the risk assessment.
        1. **I recommend** that an initial characterization be allowed with the results to be shared with NIH to determine the appropriate Risk Group level.
    ii. Upon the Implementation Date of this Policy, what is the expectation for research with the many agents (especially bacteria and fungi) that are not listed in the BMBL, and are typically handled at BSL1 or BSL2?
        1. Are researchers expected to have obtained approved from the NIH by the Implementation Date? Does NIH OSP have the personnel to review and approve the requests that they will be inundated with?
c. **Section IV-2 (Research That Requires IBC Review and Approval Before Initiation): *Research involving RG3 or RG4 wild-type biological agents.***
    i. No comments on this section.
d. **Section IV-2: *Research with primary cells that may be contaminated by adventitious agents.***
    i. As noted above, the Policy does not define adventitious agents. Therefore, entities will be uncertain how to comply with this regulation.
    ii. If the intention of the Policy is to regulate primary cells that may be contaminated by bloodborne pathogens:
        1. **We recommend that:** This should not be regulated by this Policy as long as the entity is complying with OSHA Bloodborne Pathogens Standard or its equivalent.

2. **We recommend that:** If it must be regulated by this Policy, it should not fall under the category of requiring IBC approval and should at most be in Section IV-3, where delegated review is permitted.

iii. If the intention of the Policy is to regulate primary cells that may be contaminated by any unknown biohazard (including clinical or field samples):
   1. The recommendation is that the sample undergoes genetic testing and analysis initially or is characterized at high or maximum biocontainment.

e. **Section IV-2: *Research with wild type or genetically modified RG2 biological agents for which lower containment is requested, or research with wild type or genetically modified RG3 or RG4 biological agents that NIH has previously approved to be conducted at lower containment.***
   i. The Policy implies that there will be a workflow of (1) an entity submits an initial request for NIH to lower containment involving wild type or genetically modified RG3 or RG4 biological agents, (2) NIH will make a determination on whether that lower containment is appropriate, (3) NIH will be responsible for publishing approved determinations of appropriate lower containment for these agents, (4) subsequently, research involving these agents may be approved by the IBC alone (without NIH approval).
      1. This workflow should be expressly stated in the Policy to minimize confusion. This includes a clear statement that once NIH has made the determination and published it, other entities will not be required to obtain NIH approval.
      2. The method by which NIH will publish these determinations should be described, including the minimum time frame (e.g., determinations will be published within 3 months).
      3. The Policy should be clear on how much information will be released with these determinations (will it include information that will make sensitive information readily available to foreign adversaries?)

f. **Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): *Research conducted with transgenic organisms at BSL-1/ABSL-1.***
   i. The purchase and transfer of transgenic rodents requiring BL1 containment is exempt (Appendix C-VII). Further, the generation of BL1 transgenic rodents (Appendix C-VIII) is exempt in the NIH Guidelines. In 2011, NIH deemed that "… these breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk." (January 19, 2011, Federal Register, January 19, 2011 (76 FR 3150)). As

documented in NIH guidance documents, the subsequent use of these BL1 transgenic rodents is also exempt (https://osp.od.nih.gov/wp-content/uploads/2022/11/Animal_Activities_Table.pdf). The same risk assessment should apply today, and the Policy should not require that work with transgenic rodents that can be housed at ABSL1 be approved by the IBC.

ii. As noted previously, there is no definition of *organism* in the Policy. Therefore, we recommend changing this to *animal* in this section.

iii. We understand that research with other transgenic animals has not had the time to demonstrate the same safety track record as transgenic rodents and therefore should continue to require IBC approval before that research is conducted.

iv. **We recommend that this be re-written** as: Research conducted with transgenic animals at BSL-1/ABSL-1, other than transgenic rodents.

g. **Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): *Research with genetically modified RG1 biological agents.***

i. Certain research (not requiring NIH-OSP approval and not involving DNA from RG3, RG4, or restricted organisms) with specific risk group 1 biological agents is exempt in the Guidelines (Appendices C-II, C-III, C-IV, and C-V), having been determined by the NIH Director to not present a significant risk to health or the environment. The Category here (research with genetically modified RG1 biological agents) is in contradiction to this determination and would require that work that was previously exempt now require IBC approval.

ii. **We recommend that this category be re-written as:** Research with RG1 biological agents is exempt as stated under the current policy.

h. **Several sections, including Section IV-2: *Research involving genetically modified cells, viruses, or organisms, other than plants (e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs)* and Section IV-3: *Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes***

i. An exemption for recombinant DNA molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in tissue culture has existed at least since the Federal Register Notice in 1995 (Effective June 24, 1994, Published in Federal Register, July 5, 1994 (59 FR 34472)). The NIH Director has therefore determined that such experiments do not present a significant risk to health or the environment. While a single researcher registering for this work would not be a significant burden, the total number of registrations will constitute a significant collective administrative

burden on the IBC and researchers that is not commensurate with the very low biosafety risk.

ii. **We recommend that an exemption be added.**

i. **Section IV-3: *Research with biological toxin proteins not on the Select Agent list*.**
   i. The policy needs to be written clearly and concisely, which this category does not accomplish. As written, this would include food allergens, since they cause harm to humans, yet there is no indication that this is intended.
   ii. **We recommend that this be re-written as:** Research with biological toxin proteins with an LD_{50} in vertebrates of <100 micrograms per kilograms of body weight.
   iii. Additionally, a list of toxins currently classified under this category should be provided in the Policy.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).
   a. Risk Group assignments have been removed from the NIH Guidelines and are not comprehensively provided in the BMBL. NIH should provide a definitive source or clear criteria for assigning Risk Groups to non-recombinant agents. Without standardized Risk Group classifications, institutions may reach different conclusions for the same agent, reducing consistency across the research community.
   b. Please provide the biosafety rationale and supporting evidence that prompted the inclusion of additional oversight requirements for research involving insect cell lines, non-human/NHP cell lines, and pathogens that are not capable of causing disease in humans, including immunocompromised individuals. Clarification of the specific risks, incident history, or emerging concerns that necessitate these requirements would help the research community understand the basis for the policy change and assess whether the proposed oversight is proportionate to the actual biosafety risk posed by these systems.
   c.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
   a. Additional clarification is especially in consideration of collaborations and/or contracts between non-NIH funded and funded institutions.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.
    a. The proposed definition of an incident appears overly inclusive and may capture events with minimal biosafety significance. A broad incident definition could result in unnecessary reporting requirements, diverting resources from investigating and addressing more consequential biosafety events.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.
    a. Refine the definition of a reportable incident and provide clearer thresholds for reporting to support a risk-based, consistent approach across institutions.

7. Other Comments
    a. The responsibilities of the institution (Section III-A) includes the following text (emphasis added) regarding records retention:
    The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states “the recipient and subrecipient must retain all Federal award records for **three years from the date of submission of their final financial report**.”
        i. The Policy is assuming that all IBC records are from projects that are NIH funded. The Policy has failed to consider projects that are not NIH funded and therefore will never submit a final financial report. As written, such IBC records may never be disposed of, which is either an oversight or egregious regulatory overreach. **This language needs to be changed.**
        ii. We recommend the following language:
    The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states “the recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report.” In the case of IBC records unrelated to Federal awards or where a final financial report is not submitted, it is unclear if documentation must be maintained for 1 year after IBC approval expires. This point need clarification.

8. Research with primary cells that may be contaminated by adventitious agents.

a. Provide a definition of adventitious agents.
b. Provide rationale on why primary cells require full IBC review, when wild-type (RG2/BSL2) agents can be reviewed through delegate review. The bulk of adventitious agents are categorized as risk group 2/BSL2 agents when isolated, cultured or purified, by definition this would imply that these agents can be reviewed and approved by delegate review.
c. For known clinical samples of higher risk group agents (Brucella, Herpes B, Mtb) the BMBL recommends BSL-2 practices, containment equipment, and facilities are recommended for routine handling of clinical specimens of human or animal origin. Why can't delegate review be assigned to these types of samples, with caveat that if samples are positively identified and research will continue, then full IBC review will be required?
d. Should this bullet be changed to highlight unscreened field or human samples from regions of endemic infections with RG3 and RG4 biological agents?

Reasons to remove from the scope of the Policy

- The work does not pose an appreciable risk to human health or to the environment.
- While registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk.
- Personnel who do not have access to biohazards, nor the ability to gain possession of biohazards, should not subject to the Policy. This is egregious regulatory overreach. As written, the individuals to whom this regulation will apply is broad and vague, which will lead to entities wasting time and effort to identify individuals, overtraining these individuals, and likely still being unable to fully comply with this poorly-written and obviously overreaching regulation. We strongly object to this requirement which will add significant burden to entity's without providing increased safety or security of biohazards.
    - What benefit is there in training an individual who performs administrative functions but does not have access to biohazards? How will training these individuals increase the safety or security of biohazards? This is a waste of resources with no clear benefit.
- Second, will entities be required to retroactively go back and add this information to their current inventory written records? How do the regulators expect this to be accomplished?
- This addition to the regulation will set entities up for failure, with no clear benefits to our biosafety programs.

- The Summary provided in the Policy does not provide an outlined justification for any of the following language changes to xxx. Thus, it is unclear why these changes are being proposed, how they will enhance the protection of human, animal, and plant health and safety, or how it will reduce the likelihood of the accidental or intentional release of a biohazard.

Issues to identify

- The definition is poorly written; regulatory language should be stated in clear, plain language. Such detailed examples should not be used in the regulatory language; if they are required, the original regulatory language is not sufficient and should be revised.
- Regulatory language should clearly and succinctly state a performance-based standard, which this definition fails to accomplish.
- Entities will be uncertain how to comply with this regulation, leading to chilling effects on the research community, additional administrative burden, and unintentional failures to comply.
- We recommend the following definition, based on xxx:
- The proposed definition removes the entity's ability to perform internal risk assessments to determine risk, thereby making all incidents involving biohazards reportable regardless of actual risk of escape and/or occupational exposure. The regulation must allow for the entity to perform risk assessments; it is important to recognize a risk assessment encompasses the whole picture of the event, not a single data point as these definitions imply. Risk assessments for events that may have resulted in an escape or potential occupational exposure are conducted within minutes to hours of potential exposure(s) and often incorporate a whole team of SMEs (biosafety, medical professionals, scientists, engineers) depending on the event to evaluate if the event resulted in escape of pathogen and/or if there was risk of occupational exposures.
- The additional reporting requirements will not enhance the protection of human, animal, or plant health and safety, reduce the likelihood of accidental or intentional release of a biohazard, or increase the probability that a release will be prevented from occurring.
- This change in definition will result in considerable administrative burden for entities with no real change in outcome or reduction in risk.
- Escape of a biohazard outside of primary containment should not require reporting unless a risk assessment has determined that the event resulted in a biohazard escaping beyond the defined biocontainment boundary (following the same definition in the FSAP HVAC policy statements) and/or causing an occupational exposure.

Good feedback

- This is a well written definition. Clear, concise, and with plain meaning. We support adding this definition to the regulations.

As stated previously, I support the replacement of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) as many of my colleagues do. However, there are several areas of ambiguity in the proposed Policy that could lead to confusion and an unintended massive increase in the burden placed on IBC and researchers which will have the chilling effect of hindering research progress. I don't believe that is the goal of this new Policy.

Thank you for your consideration.

153. WCG Clinical, Inc.

I am responding: On behalf of an organization

Name: Christopher Doyle

Name of Organization: WCG Clinical, Inc.

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Other

Role - Other: Sr. Director, IBC Services

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): WCG Clinical

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see the attached comments.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see the attached comments.

3. Continued utility of Risk Groups: Please see the attached comments.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see the attached comments.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see the attached comments.

6. Other feedback relevant to this resource: Please see the attached comments.

Uploaded File: Comments-from-WCG-Clinical-Draft-NIH-Biosafety-Policy-10-13-2026_esigned_.pdf

Description: Comments on the Draft Biosafety Policy from WCG Clinical, Inc.

October 13, 2026

NIH Office of Science Policy

Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Response to NOT-OD-26-112 and 91 Fed. Reg. 176

We commend NIH for modernizing biosafety oversight and for its emphasis on transparency and risk-calibrated review. Our comments address the scope of the Policy (including its definitions) and the administrative burden of the IBC provisions, including the meeting minutes template.

Scope and Definitions:

i. The existing scope of NIH Guidelines extends to clinical trials conducted with gene transfer products developed with NIH funding. For example, when an academic medical center develops a product with NIH funding, a clinical trial of that product may be conducted at the originating institution and also at community clinics. Under current rules, such clinical trials require IBC oversight at all locations in the USA as long as research collaboration or contractual agreements apply. This means that staff, visitors, and the public near the community site where the product is being tested have equal and equitable protection of IBC oversight compared to staff and visitors at the academic medical center where the product was developed. This scope of applicability for clinical trials should be preserved for any new policy.

ii. The Draft Policy states, "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained."

This sentence could be construed to limit the scope of the Draft Policy to the point of irrelevancy. There are innumerable federal agencies, and any research in the US is also under the regulation or purview of multiple agencies, such as OSHA, EPA, CDC, and/or EEOC. The purview of the Equal Employment Opportunity Commission should not abrogate requirement for IBC review.

iii. The Draft Policy defines genetic modification as the "introduction of stable alterations into the genome by passaging, reassortment, chemical or radiological means." With regard to passaging, this would encompass almost all cell biology. Any passaged cell in cell culture will undergo some stable alteration, albeit non-deliberate and non-targeted. A more relevant definition could be "deliberate introduction of stable alterations". Inclusion of reassortment (especially with regard to influenza viruses) as form of genetic modification will be an improvement over current NIH Guidelines.

iv. The April 2024 revision to the NIH Guidelines (Section III-C-1) recognized that certain materials warrant oversight because they "[p]ossess biological properties that enable introduction of stable genetic modifications into the genome (e.g., cis elements involved in integration, gene editing)." The Draft Policy retains this concept in its definition of "genetic modification." However, Section II applies the definition only to "[c]ells, viruses, or organisms, other than plants, that have been genetically modified." It is therefore unclear whether the genome-modifying materials themselves are covered. These include gene-editing reagents delivered as nucleic acids, ribonucleoprotein complexes, or proteins, and non-viral and nanoparticle-based delivery systems. Such materials may never be a "genetically modified cell, virus, or organism" until after use, and some (e.g., Cas9 or base-editor protein) are not nucleic acids. The qualifier "known or potential risk to human health" adds further uncertainty. We recommend revising the scope of the Draft Policy to include "products or materials, regardless of composition or delivery method, that are intended to modify the genome of a cell, virus, or organism."

v. Extending the scope to include wild-type biological agents, as proposed, is a good idea.

Administrative Requirements and Meeting Minutes

We support NIH's transparency goals. We are concerned, however, about the cumulative administrative burden that would be placed on institutions, many of which are already struggling with research-related staffing and funding shortages.

i. The Draft Policy adds several recurring obligations to existing IBC work that would fall on IBC administrators and biosafety staff. Smaller institutions and those with a single part-time IBC coordinator will be affected most. The risk is that limited staff time will shift from substantive biosafety review to formatting, redaction, and web maintenance.

ii. The mandatory minutes template is too rigid and unnecessary. A single prescribed format cannot fit the range of institutions, committee structures, and protocol volumes that NIH funds. Institutions already keep minutes documenting quorum, conflicts of interest, deliberations, and determinations. Reformatting them adds work without improving biosafety. Instead, we suggest NIH allow institutions to keep their existing minutes formats, with NIH specifying only a minimum set of required elements.

iii. With regard to transparency, such a system means the public would have to search thousands of separate institutional websites to obtain information. Instead, we suggest NIH create a centralized online IBC meeting minutes database, where institutions would submit approved, appropriately redacted minutes through one portal, and NIH would make them available for public viewing. This would allow the public to search and compare IBC meeting minutes in a single repository, reduce institutional burden, and give NIH a single source for oversight and identification of biosafety-related trends.

Thank you for the opportunity to comment. We are happy to clarify any of our recommendations with NIH as needed.

On behalf of WCG Clinical, Inc.,

[redacted]

Christopher Doyle, PhD

Sr. Director, IBC Services

154. Mr. M

I am responding: On behalf of myself

Name: Mr. M

Name of Organization: State University / BSAA Member

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Response.pdf

Recommendations to the National Institutes of Health Office of Science Policy

We support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the

documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a

convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

155. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.
2. Scope definitions and implementation

Policy reference Section II
Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered

research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.
Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Institutional accountability and Biosafety Assurances

Policy reference Section III A
Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs.

Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and

administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

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3. Continued utility of Risk Groups: Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

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4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: IBC establishment functions and operations

Policy reference Section III B
Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

6. Other feedback relevant to this resource: N/A

156. Martin Reyes

I am responding: On behalf of myself

Name: Martin Reyes

Name of Organization: UC Merced

Type of Organization: Academic Institution

Role: Other

Role - Other: research Adminstrator

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I agree and support with the comments submitted from COGR

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I agree and support with the comments submitted from COGR

3. Continued utility of Risk Groups: I agree and support with the comments submitted from COGR

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I agree and support with the comments submitted from COGR

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I agree and support with the comments submitted from COGR

6. Other feedback relevant to this resource: I agree and support with the comments submitted from COGR

157. Harold Burgess

I am responding: On behalf of myself

Name: Harold Burgess

Name of Organization: Eunice Kennedy Shriver National Institute of Child Health and Human Development, Division of Intramural Research

Type of Organization: Government Agency

Role: Investigator/Researcher

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Developmental Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Thank you for the opportunity to comment on the draft NIH Biosafety Policy. My laboratory studies the neuronal basis of neuropsychiatric disorders by studying how signaling between neurons is disrupted in zebrafish genetic models. In order to visualize parts of the nervous system in fish, we routinely make new transgenic lines by injecting plasmids grown in standard E Coli strains, and inject guide RNAs for CRISPR experiments, to introduce patient mutations. Over the course of a year, we create around 60 new plasmids (including intermediates) used to generate these transgenic fish, and test a similar number of guide RNAs, each of which we expect to induce novel genome mutations. Other labs in my field would use a roughly similar number of reagents. None of the work we do involves dual-use reagents or viruses. These experiments are extremely low-risk - in more than 20 years of research, I am unaware of public health hazards arising from this kind of research.

I respectfully ask NIH to consider the cumulative burden. Obtaining advance approval for each plasmid clone and guide RNA experiment is likely to take around 30 minutes of time, considering the need to assemble documentation, interact with the submission system and check for approval. Under the proposed changes, I anticipate spending around 60 hours per year on obtaining approval for my lab's genetic experiments. Few biomedical research labs have specialized administrative support that could help with this burden, which will therefore fall on lab heads and senior staff who have responsibility for laboratory administration. This will cut deeply into time that would be otherwise spent on conducting and analyzing experiments and mentoring junior staff.

For research that presents a biosecurity hazard, stringent oversight is essential. But for the well-established practices involved in ordinary plasmid cloning and zebrafish genetics, there is virtually no additional protection that will be gained from the new draft policy. I would be grateful if NIH would preserve an exemption for low-risk activities and make it clear that a review concluding that activities are

low-risk may cover a laboratory's entire research program. This would help protect to safety while making the best use of public resources by allowing scientists to focus their time where it can make the greatest difference.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

158. University of Pittsburgh

I am responding: On behalf of an organization

Name: Bill Yates

Name of Organization: University of Pittsburgh

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed scope is too narrow. Section II defines research involving biohazards by reference to known or potential risk to human health, removing genetically modified plant research and agricultural and animal-restricted pathogens from Institutional Biosafety Committee (IBC) oversight. This weakens local protection of personnel, the community, and the environment, and is inconsistent with a One Health approach.

Other federal frameworks do not replace local review. The U.S. Department of Agriculture (USDA) Biotechnology Regulatory Services (BRS), USDA Animal and Plant Health Inspection Service (APHIS), and the Food and Drug Administration (FDA) regulate importation, interstate movement, environmental release, and product approval.

Work that could fall outside any local oversight includes:

• Genetically modified plants and plant-associated microbes in growth chambers and greenhouses, where containment prevents escape of transgenes, pollen, seed, or modified pests.
• Animal-restricted pathogens (e.g., porcine reproductive and respiratory syndrome virus, Marek's disease virus), where release could harm livestock, wildlife, and the agricultural economy without causing human disease.
• Genetically modified arthropods and aquatic species, including gene drive organisms, where the primary risk is ecological.
• Agents with uncharacterized zoonotic potential (e.g., novel animal coronaviruses or influenza viruses of animal origin), not known to cause human disease when the work begins.

We recommend that NIH define biohazards to include genetically modified organisms, biological agents, and toxins posing a known or potential risk to human, animal, or plant health or to the environment. Risk-based tiering of review, rather than excluding them from scope, would reduce the burden while preserving local oversight.

DEFINITIONS REQUIRING CLARIFICATION

The draft defines an “emerging agent or organism” as “[a]n agent or organism newly identified in nature.” That phrase carries the entire definition and is itself undefined. It is unclear whether it applies only to previously unknown agents or also to new strains, variants, and reassortants of known agents, and when an agent ceases to be newly identified. The distinction is consequential: under Section III-B, an IBC may not approve research with an emerging agent whose Risk Group classification or containment level is not available in Biosafety in Microbiological and Biomedical Laboratories (BMBL) until NIH authorizes it.

The 2009 H1N1 pandemic influenza virus illustrates the problem. The Centers for Disease Control and Prevention (CDC) initially recommended Biosafety Level 3 (BSL-3) containment because the emerging strain might cause more severe disease in specific populations than circulating strains; as risk assessment information accumulated, the recommendation moved to BSL-2 with enhancements, and then to BSL-2 once updated vaccines were available. Had such a strain required NIH authorization before work began, the research response would have been significantly delayed, slowing development of diagnostics, vaccines, and medical countermeasures when speed matters most. We recommend that NIH:

• Define the term “emerging agent or organism” precisely, including whether it covers new strains or variants of known agents and at what point the designation ends.
• In Sec. III-B, change "The IBC may not approve such research until authorized by NIH AND any other applicable Federal, State, or local entities" to "The IBC may not approve such research until authorized by NIH OR other cognizant Federal agency and any other applicable State or local entities."

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): We support the provision in Section IV-2 that deliberately transferring a clinical product into a participant under an FDA-regulated individual patient expanded access Investigational New Drug (IND) application or protocol, including for emergency use, is not research subject to this Policy and does not require IBC review. This avoids delays where a specific patient’s treatment is at stake.

We recommend extending a risk-based approach to clinical research under an IND more generally. FDA’s IND review addresses product quality and manufacturing, preclinical safety data, and participant protection; Institutional Review Board (IRB) review addresses human subject protections. A separate IBC review before initiation adds burden without corresponding safety benefit.

FEDERAL AUTHORIZATION FOR EMERGING, NOVEL, AND ZOONOTIC AGENTS

Section III-B requires institutions to petition NIH for the minimum biocontainment level for emerging, novel, or zoonotic agents whose Risk Group classification or containment level is not available in the BMBL, and provides that the IBC may not approve such research until NIH authorizes it; Section IV-1 places this research in the category requiring NIH approval. This could significantly delay public health preparedness and pandemic response.

SARS-CoV-2 illustrates the concern. CDC began issuing health advisories and guidance for clinicians and

clinical laboratories in January 2020; the NIH Office of Science Policy (OSP) did not issue guidance for handling and processing specimens until May 2020. During that interval, our infectious disease researchers began work immediately under our approved biosafety program, including expedited IBC review and review of safety testing of inactivated genomic material before transfer to our affiliated health system's clinical laboratories. That material validated an emergency-authorized test critical to the high level of local testing available early in the pandemic. Waiting for NIH authorization would have prevented this work.

The requirement also sits uneasily with NIH's expectations of the National and Regional Biocontainment Laboratories, which may be expected to realign their activities rapidly during a national emergency and to make their facilities, expertise, and resources available to support response efforts. They cannot do so if work with the emerging agent must await federal authorization. We recommend that NIH:

• Recognize other authoritative guidance. While NIH completes its approval process, allow work to begin on a provisional basis under biocontainment guidance for clinical and research laboratories from CDC, USDA APHIS, the World Health Organization, or comparable authorities, in addition to the BMBL.
• Create an institutional assurance pathway. Allow institutions to register a biosafety assurance permitting work with emerging and novel agents at the highest available biosafety level, with local IBC approval and simultaneous notification to NIH OSP, to support development of diagnostics and medical countermeasures.

DELEGATION OF REVIEWS

We support the provision in Section IV-3 allowing low-risk research to be reviewed through a delegated process. It will improve IBC efficiency and allow convened meetings to focus on higher-risk activities. We recommend two modifications:

• Wild-type Risk Group 1 agents. Delegated review should include wild-type Risk Group 1 agents capable of causing disease in animals, plants, and insects, reinforcing local IBC oversight of the institutional biosafety program as a whole.
• Cell lines. The provision for delegated review of "research with well-characterized cell lines" should read "well-established and well-characterized" cell lines. Misidentified cell lines and unrecognized contamination with adventitious agents are well documented, as noted in NOT-OD-17-068, Reminder: Authentication of Key Biological and/or Chemical Resources.

THREE-YEAR DE NOVO REVIEW

Section III-B provides that IBC approval should not exceed three years, after which a de novo registration submission and review is required. This adds significant burden for investigators and IBCs with little apparent benefit, since protocols must already be amended whenever agents or procedures change. The same assurance can be achieved through two mechanisms:

• Modifications. Require submission and review of a modification before any change in agents or procedures.

• Annual attestation. Require investigators to review each protocol annually, attest that it accurately describes their current work, and affirm that unanticipated results and incidents will be reported to the IBC immediately.

The requirement may also be counterproductive: investigators may respond by providing less detail in their protocols, reducing the quality of IBC risk assessments, and repeated review of unchanged protocols could reduce the attention IBCs give to new ones.

3. Continued utility of Risk Groups: Both designations should be retained, because they answer different questions. Risk Groups establish a baseline for evaluating agent-specific risk, tied to the parent organism — particularly valuable for genetically modified microorganisms — and account for risk both to the individual laboratory worker and to the community. Biosafety levels establish a baseline of risk-mitigation measures that allow work to proceed safely, including training, occupational health, facility design, engineering controls, and personal protective equipment. They are keyed to an agent's ability to cause disease in healthy adults, with enhancements for agents that can also cause disease in agricultural animals or plants. Both feed into the cycle of risk assessment, mitigation, and communication, and should be harmonized as much as possible.

HARMONIZATION AND THE PETITION PROCESS

It is unclear how NIH's biocontainment determinations under Section III-B will be distributed to other institutions, and whether they will be harmonized with the BMBL and other authoritative references in a timely way. Without a mechanism for publishing determinations, every institution must petition separately for the same agent, and institutions will reach different containment decisions for identical work.

Harmonization gaps already exist between the NIH Guidelines and the BMBL for arboviruses, where the American Committee on Arthropod-Borne Viruses Subcommittee on Arbovirus Laboratory Safety is the authoritative reference. We recommend that NIH publish all biocontainment determinations and reconcile Risk Group classifications with the BMBL and agent-specific authoritative references on a defined schedule.

CONTAINMENT REQUIREMENTS FOR HIGHLY PATHOGENIC AVIAN INFLUENZA LINEAGES

Section V-E requires BSL-3 enhanced containment and an occupational health plan for experiments with influenza viruses containing genes or segments from 1918–1919 H1N1, human H2N2 (1957–1968), and highly pathogenic avian influenza (HPAI) H5N1 strains within the Goose/Guangdong/96-like H5 lineage. Additional HPAI lineages have since emerged, including H7NX viruses and H5NX strains in sub-Saharan Africa, and work with viruses containing their genes or segments warrants the same containment. Under the Federal Select Agent Program, work with HPAI viruses is regulated as a biological select agent or toxin unless specifically exempted. To mitigate community, environmental, and economic risks, and to avoid requiring policy amendments each time a new lineage emerges, we recommend that NIH remove specific lineage designations and refer simply to highly pathogenic avian influenza viruses.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): As an NIH-funded institution, we have no comments on this section.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: MEETING MINUTES TEMPLATE

The level of detail required for meeting minutes creates a research security risk. Section III-B requires approved minutes to be posted on a public-facing institutional webpage, and Section III-A requires minutes and incident reports to remain posted for at least five years and be available on request. Minutes prepared to the template's standard would place in the public domain a consolidated record of which high-consequence agents an institution holds, which laboratories and buildings house them, the procedures used to manipulate them, and the containment and security measures in place. No single element may be sensitive alone; aggregated in a standardized, publicly posted document across every institution conducting this research, they constitute a significant conflict with the research security and Operations Security (OPSEC) objectives outlined in NIST IR 8484.

This runs counter to federal policy. Federal research security requirements, Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC/PEPP) oversight, and the Federal Select Agent Program (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) all ask institutions to tighten control over exactly this information; select agent registration details, facility security plans, and inventory locations are protected from disclosure for well-established reasons. A template requiring public posting of agent identity, location, and methods would substantially undo that protection for work subject to IBC review, and would do so uniformly, giving a hostile actor a single reliable format to work from at every institution in the country.

The same requirement exposes unpublished federally funded research. Beyond trade secret and commercial information, detailed protocol descriptions would allow competing laboratories, domestic or foreign, to reconstruct unpublished work. Redaction cannot resolve this at reasonable cost: IBC staff are not positioned to judge which elements are proprietary or sensitive, so principal investigators must redact every protocol, adding to the burden the template already imposes. The detail requested is essentially equivalent to posting full protocols on an institutional website.

Detailed minutes also create personnel and facility security risks for research in sensitive areas, including animal models — particularly nonhuman primates — and human pathogen research. Groups that politicize this work circulate such material on social and conventional media. Redacting principal investigator names provides limited protection: the research described is usually sufficient to identify the laboratory, and facility directories then locate it. Our investigators and colleagues at peer institutions have experienced protests and threats of violence following similar disclosures.

The likely result is less information in protocols, not more: if investigators anticipate that agent, location, and procedural detail will be published, some will provide less of it, degrading the quality of IBC risk assessment and mitigation — the opposite of the policy's intent.

We recommend that NIH:

• Limit the content of posted minutes to the committee's determinations and the basis for them, without agent-specific, location-specific, or procedural detail.
• Provide fuller records to NIH and oversight bodies rather than to the public, preserving federal visibility without creating a public compilation of agents, locations, and methods.

INCIDENT REPORTING TEMPLATE

Requiring all incident reports to be posted, including Biosafety Level 1 and Animal Biosafety Level 1 (BSL-1/ABSL-1) incidents and bites or scratches from animals housed at ABSL-1, appears to advance transparency. In practice it duplicates the requirement that incident summaries appear in posted minutes and that complete reports and committee documentation be provided on request. It is unclear what additional benefit full posting provides.

The security concerns above apply with greater force here. An incident report identifies an agent, a location, and a specific failure of containment or practice at a specific facility. A public archive of such reports maps, for every institution, where the material is and where the weaknesses are.

Posting low-risk incidents also works against responsible risk communication. Consider an ABSL-1 transgenic rodent bite where the IBC determines the risk to the individual is low — limited to potential transfer of adventitious agents to the wound — and the risk to the community and environment is very low. Given how widely transgenic rodents are used, posting full reports for such events dilutes public attention to incidents that genuinely warrant it. That threshold also exceeds what other federal authorities require: under the Occupational Safety and Health Administration (OSHA) recordkeeping rule (29 CFR § 1904.7), an injury treated with first aid, such as flushing a wound and applying a bandage, is not recordable, and such treatment remains first aid even when administered by a licensed health care professional. We recommend that NIH:

• Allow posted minutes to serve as the record for BSL-1/ABSL-1 and BSL-2/ABSL-2 incidents and incidents involving transgenic animals housed at ABSL-1, reserving fuller reporting for incidents posing greater potential risk to personnel, the community, and the environment.
• Align the posting threshold with OSHA practice, so that incidents resolved with first aid, including first aid administered by a health care professional, are captured in committee minutes rather than as separately posted reports.
• Rely on the National Biosafety Data and Safety Analysis Center for trend analysis. We strongly support the Section III-C provision for voluntary, confidential, de-identified reporting of near-misses and secondary failures, and the assurance that NIH will not use voluntarily submitted data for enforcement or funding action. A de-identified national repository, modeled on the Department of Energy's OPEXShare and the NASA Aviation Safety Reporting System, will identify incident trends across institutions far more effectively than public posting of individual low-risk reports, and without the security consequences. NIH should expedite its implementation and treat it, rather than local public posting, as the mechanism for low-risk incident data.

6. Other feedback relevant to this resource: The definitions of "emerging agent or organism," "novel agent or organism," and "genetic modification" determine whether research requires federal or local review, and when that review must occur relative to the start of work. As drafted, they are not precise

enough to apply consistently, and ambiguity in any of them creates uncertainty about both the reviewing body and the permissible timeline.

Some cases are clear: mirror organisms and fully synthetic microorganisms plainly meet the definition of a novel agent, as organisms not existing in nature and deliberately designed. What remains unclear is whether a newly identified strain of a currently circulating, endemic agent is an emerging agent, since it has only recently been identified in nature. If it is, Section III-B appears to require NIH authorization before an IBC may approve the work whenever the strain's containment level is not available in the BMBL. Given how routinely new strains of endemic agents are identified, this determines whether a substantial volume of ordinary research is redirected to federal review. The definition of genetic modification raises a parallel question, since it extends to stable alterations introduced by passaging, reassortment, or chemical or radiological means — so a wide range of routine laboratory work could be treated as genetic modification.

Worked examples drawn from well-known case studies would be valuable to IBCs, particularly where they illustrate how to facilitate critical public health research safely and securely rather than only where to apply the most restrictive option. We recommend that NIH:

• Define each term explicitly, with particular attention to whether a newly identified strain of an endemic agent falls within emerging, and at what point an agent ceases to carry that designation.
• Publish worked scenarios mapping representative agents and modifications to the applicable review pathway and timing, including cases that resolve to local IBC review.

Uploaded File: NIH_Biosafety_Policy_Comments.pdf

Description: Formatted version of comments entered into text boxes

Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

The proposed scope is too narrow. Section II defines research involving biohazards by reference to known or potential risk to human health, removing genetically modified plant research and agricultural and animal-restricted pathogens from Institutional Biosafety Committee (IBC) oversight. This weakens local protection of personnel, the community, and the environment, and is inconsistent with a One Health approach.

Other federal frameworks do not replace local review. The U.S. Department of Agriculture (USDA) Biotechnology Regulatory Services (BRS), USDA Animal and Plant Health Inspection Service (APHIS), and the Food and Drug Administration (FDA) regulate importation, interstate movement, environmental release, and product approval.

Work that could fall outside any local oversight includes:

- Genetically modified plants and plant-associated microbes in growth chambers and greenhouses, where containment prevents escape of transgenes, pollen, seed, or modified pests.
- Animal-restricted pathogens (e.g., porcine reproductive and respiratory syndrome virus, Marek's disease virus), where release could harm livestock, wildlife, and the agricultural economy without causing human disease.
- Genetically modified arthropods and aquatic species, including gene drive organisms, where the primary risk is ecological.
- Agents with uncharacterized zoonotic potential (e.g., novel animal coronaviruses or influenza viruses of animal origin), not known to cause human disease when the work begins.

We recommend that NIH define biohazards to include genetically modified organisms, biological agents, and toxins posing a known or potential risk to human, animal, or plant health or to the environment. Risk-based tiering of review, rather than exclusion from scope, would reduce burden while preserving local oversight.

Definitions requiring clarification

The draft defines an "emerging agent or organism" as "[a]n agent or organism newly identified in nature." That phrase carries the entire definition and is itself undefined. It is unclear whether it reaches only previously unknown agents or also new strains, variants, and reassortants of known agents, and when an agent ceases to be newly identified. The distinction is consequential: under Section III-B, an IBC may not approve research with an emerging agent whose Risk Group classification or containment level

is not available in Biosafety in Microbiological and Biomedical Laboratories (BMBL) until NIH authorizes it.

The 2009 H1N1 pandemic influenza virus illustrates the problem. The Centers for Disease Control and Prevention (CDC) initially recommended Biosafety Level 3 (BSL-3) containment because the emerging strain might cause more severe disease in specific populations than circulating strains; as risk assessment information accumulated, the recommendation moved to BSL-2 with enhancements, and then to BSL-2 once updated vaccines were available. Had such a strain required NIH authorization before work began, the research response would have been significantly delayed, slowing development of diagnostics, vaccines, and medical countermeasures when speed matters most. We recommend that NIH:

- Define the term “emerging agent or organism” precisely, including whether it covers new strains or variants of known agents and at what point the designation ends.
- In Sec. III-B, change "The IBC may not approve such research until authorized by NIH **AND** any other applicable Federal, State, or local entities" to "The IBC may not approve such research until authorized by NIH **OR** other cognizant Federal agency and any other applicable State or local entities."

2. Appropriateness of tiered oversight and calibration to risk (i.e., Federal versus local).

We support the provision in Section IV-2 that deliberately transferring a clinical product into a participant under an FDA-regulated individual patient expanded access Investigational New Drug (IND) application or protocol, including for emergency use, is not research subject to this Policy and does not require IBC review. This avoids delays where a specific patient’s treatment is at stake.

We recommend extending a risk-based approach to clinical research under an IND more generally. FDA’s IND review addresses product quality and manufacturing, preclinical safety data, and participant protection; Institutional Review Board (IRB) review addresses human subject protections. A separate IBC review before initiation adds burden without corresponding safety benefit.

Federal authorization for emerging, novel, and zoonotic agents

Section III-B requires institutions to petition NIH for the minimum biocontainment level for emerging, novel, or zoonotic agents whose Risk Group classification or containment level is not available in the BMBL, and provides that the IBC may not approve such research until NIH authorizes it; Section IV-1 places this research in the category requiring NIH approval. This could significantly delay public health preparedness and pandemic response.

SARS-CoV-2 illustrates the concern. CDC began issuing health advisories and guidance for clinicians and clinical laboratories in January 2020; the NIH Office of Science Policy (OSP) did not issue guidance for handling and processing specimens until May 2020. During that interval, our infectious disease researchers began work immediately under our approved biosafety program, including expedited IBC review and review of safety testing of inactivated genomic material before transfer to our affiliated health system’s clinical laboratories. That material validated an emergency-authorized test critical to the

high level of local testing available early in the pandemic. Waiting for NIH authorization would have prevented this work.

The requirement also sits uneasily with NIH's expectations of the National and Regional Biocontainment Laboratories, which may be expected to realign their activities rapidly during a national emergency and to make their facilities, expertise, and resources available to support response efforts. They cannot do so if work with the emerging agent must await federal authorization. We recommend that NIH:

- **Recognize other authoritative guidance.** While NIH completes its approval process, allow work to begin on a provisional basis under biocontainment guidance for clinical and research laboratories from CDC, USDA APHIS, the World Health Organization, or comparable authorities, in addition to the BMBL.
- **Create an institutional assurance pathway.** Allow institutions to register a biosafety assurance permitting work with emerging and novel agents at the highest available biosafety level, with local IBC approval and simultaneous notification to NIH OSP, to support development of diagnostics and medical countermeasures.

Delegation of reviews

We support the provision in Section IV-3 allowing low-risk research to be reviewed through a delegated process. It will improve IBC efficiency and allow convened meetings to focus on higher-risk activities. We recommend two modifications:

- **Wild-type Risk Group 1 agents.** Delegated review should include wild-type Risk Group 1 agents capable of causing disease in animals, plants, and insects, reinforcing local IBC oversight of the institutional biosafety program as a whole.
- **Cell lines.** The provision for delegated review of "research with well-characterized cell lines" should read "well-established and well-characterized" cell lines. Misidentified cell lines and unrecognized contamination with adventitious agents are well documented, as noted in NOT-OD-17-068, Reminder: Authentication of Key Biological and/or Chemical Resources.

Three-year de novo review

Section III-B provides that IBC approval should not exceed three years, after which a de novo registration submission and review is required. This adds significant burden for investigators and IBCs with little apparent benefit, since protocols must already be amended whenever agents or procedures change. The same assurance can be achieved through two mechanisms:

- **Modifications.** Require submission and review of a modification before any change in agents or procedures.
- **Annual attestation.** Require investigators to review each protocol annually, attest that it accurately describes their current work, and affirm that unanticipated results and incidents will be reported to the IBC immediately.

The requirement may also be counterproductive: investigators may respond by providing less detail in their protocols, reducing the quality of IBC risk assessments, and repeated review of unchanged protocols could reduce the attention IBCs give to new ones.

3. Continued utility of Risk Groups as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels outlined in the BMBL.

Both designations should be retained, because they answer different questions. Risk Groups establish a baseline for evaluating agent-specific risk, tied to the parent organism — particularly valuable for genetically modified microorganisms — and account for risk both to the individual laboratory worker and to the community. Biosafety levels establish a baseline of risk-mitigation measures that allow work to proceed safely, including training, occupational health, facility design, engineering controls, and personal protective equipment. They are keyed to an agent's ability to cause disease in healthy adults, with enhancements where an agent can also cause disease in agricultural animals or plants. Both are inputs to the cycle of risk assessment, mitigation, and communication, and should be harmonized to the extent possible.

Harmonization and the petition process

It is unclear how NIH's biocontainment determinations under Section III-B will be distributed to other institutions, and whether they will be harmonized with the BMBL and other authoritative references in a timely way. Without a mechanism for publishing determinations, every institution must petition separately for the same agent, and institutions will reach different containment decisions for identical work.

Harmonization gaps already exist between the NIH Guidelines and the BMBL for arboviruses, where the American Committee on Arthropod-Borne Viruses Subcommittee on Arbovirus Laboratory Safety is the authoritative reference. We recommend that NIH publish all biocontainment determinations and reconcile Risk Group classifications with the BMBL and agent-specific authoritative references on a defined schedule.

Containment requirements for highly pathogenic avian influenza lineages

Section V-E requires BSL-3 enhanced containment and an occupational health plan for experiments with influenza viruses containing genes or segments from 1918–1919 H1N1, human H2N2 (1957–1968), and highly pathogenic avian influenza (HPAI) H5N1 strains within the Goose/Guangdong/96-like H5 lineage. Additional HPAI lineages have since emerged, including H7NX viruses and H5NX strains in sub-Saharan Africa, and work with viruses containing their genes or segments warrants the same containment. Under the Federal Select Agent Program, work with HPAI viruses is regulated as a biological select agent or toxin unless specifically exempted. To mitigate community, environmental, and economic risks, and to avoid a policy requiring amendment each time a new lineage emerges, we recommend that NIH remove the specific lineage designations and refer simply to highly pathogenic avian influenza viruses.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).

As an NIH-funded institution, we have no comments on this section.

5. Comments on the draft incident reporting and meeting minutes templates.

Meeting minutes template

The level of detail required for meeting minutes creates a research security risk. Section III-B requires approved minutes to be posted on a public-facing institutional webpage, and Section III-A requires minutes and incident reports to remain posted for at least five years and be available on request. Minutes prepared to the template's standard would place in the public domain a consolidated record of which high-consequence agents an institution holds, which laboratories and buildings house them, the procedures used to manipulate them, and the containment and security measures in place. No single element may be sensitive alone; aggregated in a standardized, publicly posted document across every institution conducting this research, they constitute a significant conflict with the research security and Operations Security (OPSEC) objectives outlined in NIST IR 8484.

This runs counter to federal policy. Federal research security requirements, Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC/PEPP) oversight, and the Federal Select Agent Program (42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) all ask institutions to tighten control over exactly this information; select agent registration details, facility security plans, and inventory locations are protected from disclosure for well-established reasons. A template requiring public posting of agent identity, location, and methods would substantially undo that protection for work subject to IBC review, and would do so uniformly, giving a hostile actor a single reliable format to work from at every institution in the country.

The same requirement exposes unpublished federally funded research. Beyond trade secret and commercial information, detailed protocol descriptions would allow competing laboratories, domestic or foreign, to reconstruct unpublished work. Redaction cannot resolve this at reasonable cost: IBC staff are not positioned to judge which elements are proprietary or sensitive, so principal investigators must redact every protocol, adding to the burden the template already imposes. The detail requested is essentially equivalent to posting full protocols on an institutional website.

Detailed minutes also create personnel and facility security risks for research in sensitive areas, including animal models — particularly nonhuman primates — and human pathogen research. Groups that politicize this work circulate such material on social and conventional media. Redacting principal investigator names provides limited protection: the research described is usually sufficient to identify the laboratory, and facility directories then locate it. Our investigators and colleagues at peer institutions have experienced protests and threats of violence following similar disclosures.

The likely result is less information in protocols, not more: if investigators anticipate that agent, location, and procedural detail will be published, some will provide less of it, degrading the quality of IBC risk assessment and mitigation — the opposite of the policy's intent.

We recommend that NIH:

- Limit the content of posted minutes to the committee's determinations and the basis for them, without agent-specific, location-specific, or procedural detail.
- Provide fuller records to NIH and oversight bodies rather than to the public, preserving federal visibility without creating a public compilation of agents, locations, and methods.

Incident reporting template

Requiring all incident reports to be posted, including Biosafety Level 1 and Animal Biosafety Level 1 (BSL-1/ABSL-1) incidents and bites or scratches from animals housed at ABSL-1, appears to advance transparency. In practice it duplicates the requirement that incident summaries appear in posted minutes and that complete reports and committee documentation be provided on request. It is unclear what additional benefit full posting provides.

The security concerns above apply with greater force here. An incident report identifies an agent, a location, and a specific failure of containment or practice at a specific facility. A public archive of such reports maps, for every institution, where the material is and where the weaknesses are.

Posting low-risk incidents also works against responsible risk communication. Consider an ABSL-1 transgenic rodent bite where the IBC determines the risk to the individual is low — limited to potential transfer of adventitious agents to the wound — and the risk to the community and environment is very low. Given how widely transgenic rodents are used, posting full reports for such events dilutes public attention to incidents that genuinely warrant it. That threshold also exceeds what other federal authorities require: under the Occupational Safety and Health Administration (OSHA) recordkeeping rule (29 CFR § 1904.7), an injury treated with first aid, such as flushing a wound and applying a bandage, is not recordable, and such treatment remains first aid even when administered by a licensed health care professional. We recommend that NIH:

- Allow posted minutes to serve as the record for BSL-1/ABSL-1 and BSL-2/ABSL-2 incidents and incidents involving transgenic animals housed at ABSL-1, reserving fuller reporting for incidents posing greater potential risk to personnel, the community, and the environment.
- Align the posting threshold with OSHA practice, so that incidents resolved with first aid, including first aid administered by a health care professional, are captured in committee minutes rather than as separately posted reports.
- **Rely on the National Biosafety Data and Safety Analysis Center for trend analysis.** We strongly support the Section III-C provision for voluntary, confidential, de-identified reporting of near-misses and secondary failures, and the assurance that NIH will not use voluntarily submitted data for enforcement or funding action. A de-identified national repository, modeled on the Department of Energy's OPEXShare and the NASA Aviation Safety Reporting System, will identify incident trends across institutions far more effectively than public posting of individual low-risk reports, and without the security consequences. NIH should expedite its implementation and treat it, rather than local public posting, as the mechanism for low-risk incident data.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

The definitions of "emerging agent or organism," "novel agent or organism," and "genetic modification" determine whether research requires federal or local review, and when that review must occur relative to the start of work. As drafted, they are not precise enough to apply consistently, and ambiguity in any of them creates uncertainty about both the reviewing body and the permissible timeline.

Some cases are clear: mirror organisms and fully synthetic microorganisms plainly meet the definition of a novel agent, as organisms not existing in nature and deliberately designed. What remains unclear is whether a newly identified strain of a currently circulating, endemic agent is an emerging agent, since it has only recently been identified in nature. If it is, Section III-B appears to require NIH authorization

before an IBC may approve the work whenever the strain's containment level is not available in the BMBL. Given how routinely new strains of endemic agents are identified, this determines whether a substantial volume of ordinary research is redirected to federal review. The definition of genetic modification raises a parallel question, since it extends to stable alterations introduced by passaging, reassortment, or chemical or radiological means — so a wide range of routine laboratory work could be treated as genetic modification.

Worked examples drawn from well-known case studies would be valuable to IBCs, particularly where they illustrate how to facilitate critical public health research safely and securely rather than only where to apply the most restrictive option. We recommend that NIH:

- Define each term explicitly, with particular attention to whether a newly identified strain of an endemic agent falls within emerging, and at what point an agent ceases to carry that designation.
- Publish worked scenarios mapping representative agents and modifications to the applicable review pathway and timing, including cases that resolve to local IBC review.

159. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/13/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: This is so vague and unclear. Needs more defined definitions and how it is more tiered to decreasing bureaucracy. How it is written creates more red tape that a researcher has to navigate even for low risk research

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The biosafety team needs more oversight and empowerment it is not clear in this draft

3. Continued utility of Risk Groups: Bmbl focuses on containment not risk groups. Make the bmbl more policy that recommendations and it would hold more power

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): There's nothing here that forces private companies to comply. In fact this drives more people to go private with less required oversight

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Absolutely should not be required. This is forcing a square peg into a round hole. Required elements are fine.

6. Other feedback relevant to this resource: Needs a lot of runway too implement and not just 6 months. Needs a lot of implementation guidance and webinars to inform scientists how this affects them. Just send more red tape with little eye to safety

160. Meghan Koch

I am responding: On behalf of myself

Name: Meghan Koch

Name of Organization: Fred Hutchinson Cancer Research Center

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: the policy should not be changed. It is not appropriate. It is far too restrictive, puts too much strain on research and will impede research. It also may punish investigators for simply seeking to do fundamental biological research to understand the world around us.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): not appropriate. Too much federal involvement and too restrictive

3. Continued utility of Risk Groups: defining biohazards beyond what is already included is excessive.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): publicly outing scientists by posting mistakes will discourage discovery and detract from human health.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

161. European Research Infrastructure on Highly Pathogenic Agents (ERINHA AISBL)

I am responding: On behalf of an organization

Name: Jonathan Ewbank

Name of Organization: European Research Infrastructure on Highly Pathogenic Agents (ERINHA AISBL)

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Pandemic preparedness

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The text reads, "For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:
1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above".
There is therefore currently no definition of "biohazard". This should be rectified. A proposition is given below.

The inclusion of "Cells or organisms, other than plants, containing" "other self-aggregating proteins" (i.e. 3) is inappropriately broad and requires explicit qualification.

Managing the risks from biohazards (i.e. biorisk management) requires the overlapping elements of good biosafety and laboratory biosecurity practice (see for example, Figure 1.1 in Laboratory biosecurity guidance. Geneva: World Health Organization; 2024, a reference document reviewed before publication both by the American Biological Safety Association (ABSA) International and the US government). These include in the areas of Risk assessment, Programme management, Inventory control, Access restriction, Accountability and compliance, Reporting and response, Training and drills, Transfer and transport, Decontamination and, waste management. Section I starts, "As the world's largest public funder of biomedical research, NIH is committed to ensuring that gold-standard science is conducted under gold-standard biosafety conditions", and ends, "to help ensure the safe, responsible, and secure conduct of such research". Thus, although there is thus an implicit recognition of the complementary importance of biosecurity, it is explicitly excluded from the policy. Indeed, the word "biosecurity" only occurs once, in Section III-B, to qualify the perimeter of IRB competences. This is more than a semantic issue. We recommend that the important and inseparable role of biosecurity in the oversight of research with biohazards be reflected in a revised policy.

The inadvertent release of different classes of engineered plants has the potential to cause harm to humans (e.g. plants producing heterologous allergens), other animals (e.g. plants producing heterologous toxins), plants (e.g. invasive plants with increased fitness) and the environment. The omission of plants from the Scope does not align with normal precautionary principles. Similarly, the qualification, “other than plants” in Section IV-2 does not appear to be warranted.

The definition, “Biological agent: Bacteria, viruses, fungi or parasites that cause human disease” is more constrained than definitions that are widely used. We recommend, “A microorganism, virus, biological toxin, particle, or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity, or otherwise create a hazard to humans, nonhuman animals, or plants”. And generally, the use of the definitions provided in WHO publications, written with US government support, is recommended as this policy will have a global reach. The 2022 Global guidance framework for the responsible use of the life sciences; Mitigating biorisks and governing dual-use research” would be an appropriate source. This could also help clarify some of the current confusion regarding terms such as biohazard. [“A hazard does not become a “risk” until the likelihood and consequences of that hazard causing harm are taken into account”].

The definition of “Genetic modification” (The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:) includes, “The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means”. This is incoherent because it is trying to fit under one umbrella two distinct categories of genome modification. This could be resolved thus:
Genetic modification:
· The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
– Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
– Have the potential for one or more cycles of replication in a cell; or
– Can be transcribed or translated.
· The production of cells, organisms, or viruses with stable alterations of their genomes by passaging, reassortment, chemical or radiological means.

The qualification, “deliberately designed”, is an unwarranted restriction of the scope of “Novel agent or organism”.
The qualification, “without deliberately introduced genetic modifications” is unnecessary for the definition of “Wild type”.
“A confirmed or potential laboratory-acquired infection (LAI)” should be replaced by “laboratory-associated infection” as this also covers secondary and tertiary infections.

Taking these elements into consideration, we propose the following:
“For the purpose of the scope of this Policy, a biohazard is defined as being any of the following:
1. Wild-type pathogens;
2. Cells, viruses, or organisms, that have been genetically modified;

3. Prions, or other self-aggregating proteins associated with transmissible disease; or
4. Toxins.
Cells or organisms that are themselves not biohazards, but that harbor any one of the 4 classes of biohazard listed above are also considered to fall under the scope of this Policy".

There is an apparent gap regarding information security. For example, there is a proposed requirement for an IRB to post "all incident reports on a public-facing webpage on the website of the institution, using the required incident reporting template". While transparency is a laudable goal, certain information may be in itself a biosecurity risk and provisions need to be made to deal with such contingencies.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: The "IBC Functions" under Section III-B. Responsibilities of the Institutional Biosafety Committee (IBC), include, "Petitioning NIH for determination of the minimum biocontainment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available in the BMBL. The IBC may not approve such research until authorized by NIH and any other applicable Federal, State, or local entities". Unless the policy is intended to be used to prohibit any and all experimentation with particular future emerging or zoonotic biological agents, it would be expedient to include a provision that under exceptional circumstances, during a public health emergency, for example, allows provisional IBC approval without prior NIH authorization, if, and only if, the research is to be carried out under BSL4 conditions. This carve-out would not be appropriate for novel biological agents. Similar considerations apply to Section IV-1. Research That Requires NIH and IBC Approval Before Initiation.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: While the duties of the Biological Safety Officer (BSO) [more commonly termed simply "biosafety officer"] are given, it would be appropriate to provide guidance regarding their required competencies and experience. This applies equally to the official that "the institution must assign" "to take on these responsibilities" in the absence of a BSO.

162. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public reporting they way it is written to be done in the proposed policy crushes the culture of trust between the researchers and the Health & Safety Office of the institution. Such reporting will result in lower overall reporting of incidents to safety professionals and less outreach asking for support when things do go wrong. Safety professionals work very hard to build up these relationships with researchers at their institutions and to create that needed trust and source of support. Requiring institutions to report out all exposures with biological material and include names and details will break that trust. This is also most likely a major HIPAA violation by sharing protected information or information about an incident where others could easily search institutional website to identify they names of students, staff, and post-docs that were involved in the that incident.

6. Other feedback relevant to this resource: N/A

163. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Under organisms, are all strains of transgenic mice included? Will the NIH provide instructions on how to evaluate these strains, as the genetic material introduced to these mice are usually not hazardous or present a risk? Most transgenic mouse strains do not cause human or animal disease and there is no risk to using these animals, besides the inherent risk of the animal itself. There is no need to perform a risk assessment on these animals as far at the transgenes are concerned. Under Appendix C-VII of the NIH Guidelines, the purchase or transfer of transgenic rodents that may be housed under BL1 containment are activities that are exempt from the NIH Guidelines. What elements would need to be registered and reviewed if such animals now need to be registered? Please note that this would also be an insane burden on biosafety programs, as there are often 50+ strains of varying transgenic mice used in a single IACUC protocol. Spending time to evaluate all of these strains would bring no risk benefit to the researcher or the institution and take valuable time away from other tasks.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

164. Megan

I am responding: On behalf of myself

Name: Megan

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety professional

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Major Comments
Positive Aspects of the Draft Policy
The draft advances several important modernization goals by:
• Expanding oversight beyond recombinant and synthetic nucleic acid methodologies;
• Bringing wild-type biological agents into the oversight framework;
• Recognizing emerging technologies and novel biological risks;
• Attempting to establish more structured incident-reporting categories and timelines;
• Increasing transparency; and
• Acknowledging the need for implementation resources.
Need for Greater Interagency Harmonization
The draft frequently references other federal agencies but does not establish mechanisms for resolving overlapping jurisdictional questions or conflicting regulatory interpretations. This is particularly concerning given the continued ambiguity surrounding:
• Plant pathogens;
• Animal pathogens;
• USDA-regulated activities;
• FDA-regulated clinical activities;
• Select Agent programs; and
• Environmental release activities.
Without stronger coordination mechanisms, institutions may continue to face fragmented and inconsistent oversight requirements.
The modernization initiative appropriately seeks to broaden oversight beyond traditional recombinant DNA frameworks. However, several definitions and concepts appear to differ from terminology already used by NIH, USDA, CDC, EPA, and other federal agencies.
Examples include terminology related to:
• Novel organisms;

• Genetically engineered organisms;
• Animal pathogens;
• Plant pathogens;
• Environmental release; and
• Containment classifications.

Differences in terminology create opportunities for inconsistent interpretation and may increase regulatory burden for institutions conducting research subject to multiple federal oversight frameworks. NIH should work with partner agencies to harmonize terminology wherever possible and publish joint guidance when differences cannot be avoided. A formal interagency biosafety coordination mechanism would further improve consistency and reduce regulatory confusion.

The Policy Does Not Address Continuity of Large-Scale Biosafety Requirements

Replacing the current NIH Guidelines also raises a significant continuity question for large-scale biosafety. Appendix K currently provides nationally recognized physical-containment and operational practices for large-scale work involving viable organisms containing recombinant or synthetic nucleic acid molecules, and BMBL Appendix M expressly refers to Appendix K as a source of practices applicable to large-scale work involving both genetically modified and non-genetically modified biological materials. The proposed Policy does not state whether Appendix K will remain effective, be incorporated into binding implementation materials, be superseded by BMBL Appendix M, or be replaced by another maintained standard.

This omission could leave institutions, production facilities, and the professionals who evaluate large-scale systems without a clear federal baseline for matters such as closed systems, transfer operations, aerosol generation, inactivation, waste handling, utilities, and process-specific engineering controls. It is also notable that the draft no longer identifies large-scale work as an independent trigger for mandatory appointment of a BSO.

NIH should identify the future status of Appendix K, the applicability of large-scale containment provisions to recombinant, genetically modified, and non-recombinant biological materials, the respective status of mandatory and advisory provisions, the qualifications and institutional expertise expected for large-scale work, and the federal entity responsible for maintaining and updating this guidance.

Other-agency oversight language could be read as either substitution or duplication

The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. It does not say whether NIH-policy oversight is displaced, deemed satisfied, or remains concurrent.

This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. NIH should adopt a function-specific reliance framework rather than treating another federal program as either wholly substitutive or wholly duplicative. A federal permit, inspection, registration, accreditation, or approval may already establish particular facts concerning facilities, containment features, training, personnel qualifications, permitted activities, or required controls without resolving the entire research-specific biosafety assessment. Institutions should be permitted to incorporate and rely upon those findings for the questions they actually address while retaining IBC responsibility for experimental features or local conditions not resolved through the other process.

NIH should publish an issue-specific crosswalk identifying potentially overlapping federal programs, the functions that may be satisfied through reliance, the documentation needed to establish reliance, the

limits of that reliance, and the responsibilities that remain with the institution or IBC. This would reduce duplicative review without incorrectly treating distinct federal programs as interchangeable.

The Exclusion of Genetically Modified Plants Creates a Significant Regulatory Gap

The draft repeatedly recognizes environmental risk, unintended release, ecological impacts, environmental containment, population-level consequences, and the potential for broader environmental effects arising from biotechnology research. At the same time, genetically modified plants are expressly excluded from the scope of the policy. This exclusion is difficult to reconcile with the policy's stated objectives and risk-assessment framework.

At a minimum, genetically modified plants may present plausible food or feed safety concerns, agricultural impacts, ecological consequences, environmental persistence, gene flow, or other environmental risks that warrant institutional review and risk assessment. The draft requires IBCs to evaluate environmental risks and, in some circumstances, maintain expertise in ecological and environmental risk assessment, yet expressly excludes a major category of research capable of creating agricultural, ecological, food or feed, and other environmental consequences.

More broadly, the plant exclusion illustrates a recurring challenge throughout the draft: the absence of a clearly coordinated federal oversight framework. Federal oversight of biotechnology products is distributed principally among USDA, FDA, and EPA under the Coordinated Framework for the Regulation of Biotechnology. However, product-focused regulatory authorities do not necessarily provide continuous institutional oversight of all contained research activities preceding product development, field testing, environmental release, or commercialization. The draft does not explain whether NIH considers those product-focused authorities sufficient to replace institutional biosafety oversight during the research phase, or how occupational, containment, biosecurity, and environmental risks falling outside a defined regulatory trigger should be addressed.

If NIH intends to exclude plant research because it believes other federal agencies provide sufficient oversight, the policy should explicitly state that rationale and clearly describe where responsibility transfers from institutional biosafety oversight to other regulatory programs. As written, the policy does neither. The result is uncertainty regarding whether plant-related research falls outside oversight entirely, is expected to be reviewed under another federal framework, or remains subject to institutional review through some mechanism not described in the policy.

NIH should either incorporate appropriate oversight of genetically modified plants within the policy's scope or clearly articulate the interaction between NIH requirements and USDA, FDA, and EPA authorities, including the specific circumstances under which institutional biosafety oversight is expected, reduced, or displaced. Without a defined relationship among NIH institutional-oversight requirements and USDA, FDA, and EPA authorities, the exclusion risks creating precisely the type of ambiguity, gap, or inconsistent oversight that federal coordination is intended to prevent.

The plant exclusion is particularly notable because it represents one of the clearest examples where the draft expands discussion of environmental risk while simultaneously excluding a major category of research capable of creating environmental consequences.

Technical Comments

The policy covers “all biohazards,” but never defines “biohazard.”

Conflicting provisions: The background repeatedly characterizes the proposal as applying to “all biohazards,” and the scope defines “research involving biohazards” through a list of covered materials. However, the definitions section contains no definition of biohazard itself.

Why it matters: Institutions cannot reliably determine the boundary of the policy, especially for materials

that present environmental, animal, plant, toxicological, or occupational risks without clearly posing a human-health risk.
The scope claims to address environmental risk while largely excluding plant hazards and plant genetic modification.
Conflicting provisions: Scope is limited to risks to human health and excludes genetically modified plants. Yet IBC responsibilities require assessing risk to the environment, policy definitions include environmental considerations, and risk-assessment provisions discuss impacts on populations and the environment.
Why it matters: A genetically modified plant with ecological or agricultural consequences appears outside scope even though the policy requires IBCs to assess environmental risks. This creates a substantive gap rather than merely an editorial issue.
“Biological agent” is defined too narrowly for how the term is used
The policy defines a biological agent as bacteria, viruses, fungi, or parasites that cause human disease. That excludes nonpathogenic organisms, animal-only pathogens, plant pathogens, and agents with uncertain pathogenicity. Yet later provisions repeatedly use “biological agent” when discussing RG1 materials, zoonotic agents, genetically modified agents, environmental impacts, and organisms not currently known to cause human disease.
Suggested correction: Define biological agent neutrally, such as bacteria, viruses, fungi, parasites, and other biologically derived or replicating entities. Define biohazardous biological agent separately based on the capacity to cause harm.
The expanded-access exemption is narrower than the reasoning appears to support
A single-patient FDA-regulated expanded-access use is excluded because it is not research, but the policy does not address analogous veterinary expanded access, compassionate use, emergency investigational use outside the exact IND terminology, or activities that involve preparation and handling by research laboratories.
The key inconsistency is between a policy scope framed around “research” and operational activities that may carry the same biosafety risks but receive different treatment based on regulatory designation.
Animal hazards are treated inconsistently
The scope covers wild-type agents only when they cause disease in humans, which appears to exclude animal-only pathogens. Nevertheless:
• “Prions and self-aggregating proteins” include materials causing disease in humans or animals.
• “Zoonotic” agents are expressly defined.
• IBC membership must include animal-containment expertise under certain circumstances.
• The policy requires reporting incidents involving covered research animals.
• Risk assessment and containment provisions address animal populations and ABSL containment.
Result: The policy regulates animal-related procedures and environmental consequences, but its threshold definition may exclude the underlying animal pathogen unless it is zoonotic or genetically modified.
Toxin scope and toxin oversight do not align
Scope covers “toxins” without an express threshold, but the definition limits toxin to a protein or peptide produced by living organisms that harms humans. Section IV-2 assigns full IBC review to Select Agent toxins, while Section IV-3 permits delegated review for non-Select Agent biological toxin proteins.
Unresolved points include:
• Whether all quantities and concentrations are covered.

• Whether inactive toxin derivatives are covered.
• Whether isolated subunits are “toxins.”
• Whether nucleic acids encoding toxins are treated as toxin research, genetic modification, or both.
• Whether low-toxicity proteins technically capable of harm require delegated IBC review.
• Why peptides are included in the definition but IV-3 refers only to “toxin proteins.”

This is a major administrative-burden issue because the literal language has no de minimis or potency threshold.

Self-aggregating proteins are treated both as a broad class and as disease-causing materials

The scope covers “prions and other self-aggregating proteins,” while the definition appears limited to misfolded proteins that self-propagate and cause neurodegenerative disease. Section IV-2 then appears to require full IBC review for all prions and other self-aggregating proteins.

Inconsistency: The scope language could capture ordinary aggregating proteins, while the definition is narrower and disease-based. The policy should specify whether the category is limited to transmissible or experimentally propagating protein agents associated with disease.

“Biomedical research” is defined partly by institutional funding status rather than scientific content

The definition first refers to research within the NIH mission, but then includes NIH-supported research and non-NIH-funded research conducted at an NIH-funded institution. This blends a scientific definition with the rule establishing policy applicability.

Why inconsistent: Whether work is “biomedical research” should ordinarily turn on the nature or purpose of the work, while whether it is subject to the policy should be addressed in the applicability section. As written, identical research could be “biomedical” at an NIH-funded institution but not at an otherwise comparable non-recipient institution.

“Laboratory research” includes clinical settings, but clinical research is treated as structurally different

The definition says laboratory research includes clinical settings within BSL/ABSL 1–4 containment facilities. Later, the policy acknowledges that clinical settings generally do not conform to laboratory BSLs.

Why inconsistent: Clinical settings are simultaneously included within a BSL-based definition and described as not conforming to BSLs. A separate definition of clinical research involving biohazards would avoid forcing clinical activity into a laboratory-containment framework.

RG1 wild-type agents are excluded, but RG1 derivatives and commonplace materials are swept back in

Section IV-3 explicitly says wild-type RG1 agents are not subject to the policy, but delegated review is required for:

• genetically modified RG1 agents;
• transgenic organisms at BSL-1/ABSL-1;
• certain plasmids;
• replication-incompetent, non-integrating viral vectors;
• well-characterized cell lines; and
• non-Select Agent toxins.

This conflicts with the stated goal of removing red tape for low-risk research. The proposal expands mandatory oversight to many routine research materials that may present no greater biosafety risk than excluded wild-type RG1 organisms. The background promises streamlining, but the operative text creates mandatory pre-initiation review and subsequent reporting of delegated approvals to the IBC.

GDMO terminology is used more broadly than the definition supplied

The policy defines gene drive but does not separately define gene drive modified organism (GDMO). It

variously refers to gene drive modified organisms, gene drive modified biological agents, and GDMOs. Why this matters: BSO appointment, ecological expertise, NIH approval, and minimum BSL-2 containment all turn on whether work qualifies as GDMO research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The draft repeatedly states NIH intends to strengthen IBCs. However, the proposal primarily expands IBC responsibilities rather than authority, resources, training, accreditation, or institutional support.

Major Comments

The Draft Fails to Establish Institutional Parity for Biosafety Oversight

A central objective of the biosafety modernization initiative was to strengthen the institutional standing of biosafety oversight and move IBCs toward parity with Institutional Review Boards and Institutional Animal Care and Use Committees. Stakeholders repeatedly emphasized that effective biosafety oversight requires more than an expanded scope of review. It requires IBCs to have comparable institutional recognition, independence, authority, resources, and access to senior leadership.

The draft does not accomplish this objective. Although it substantially expands the responsibilities of IBCs, it does not establish the governance structures necessary to elevate them to a position comparable to IRBs and IACUCs. It does not require institutions to:

• Place the IBC within an appropriately senior institutional oversight structure;
• Provide the IBC with direct access to senior research leadership;
• Establish institutional independence or protections for IBC decision-making;
• Provide the IBC with authority to suspend or require modification of unsafe research;
• Define minimum staffing or administrative support;
• Provide resources proportionate to the expanded scope of oversight; or
• Demonstrate that biosafety oversight receives institutional support comparable to human-subject and animal-care oversight.

The same gap applies to the BSO. Responsibility for implementing an institution-wide biosafety program should be accompanied by institutional authority and standing commensurate with that responsibility. The draft assigns substantial duties to the BSO but does not require an organizational position that provides sufficient independence, access to senior leadership, authority to require corrective action, or protection from conflicts created by competing institutional priorities. For institutions with substantial or complex research programs, NIH should require that the senior biosafety official have direct access to executive research leadership and sufficient organizational stature to raise unresolved safety concerns without relying solely on intermediate reporting channels.

This omission is particularly significant because the draft increases institutional accountability, expands the range of research subject to oversight, and makes risk assessment more dependent on local biosafety expertise. A policy cannot meaningfully strengthen IBCs and BSOs while leaving their institutional status, independence, authority, and resourcing almost entirely undefined. Without enforceable expectations for institutional parity and leadership access, the draft risks creating a system in which IBCs and BSOs are accountable for a much broader program but remain structurally subordinate and inadequately empowered.

NIH should revise the policy to establish minimum institutional-governance expectations for biosafety programs, including:

1. Institutional placement and leadership access appropriate to the scope and complexity of the research program;
2. Documented authority for the IBC or BSO to immediately pause activities presenting an imminent

safety concern and authority for the IBC to require corrective action, modify approval conditions, or suspend research when necessary;
3. Independence protections for biosafety determinations;
4. Minimum qualifications and competency expectations for the senior BSO;
5. Staffing and administrative-support expectations based on program size and risk;
6. Direct escalation pathways to an identified senior institutional official with authority over the research enterprise, regardless of the title used by the institution; and
7. A requirement that Biosafety Assurances describe how the institution provides its IBC and biosafety program with authority, resources, independence, and institutional support comparable to other major research-oversight functions.

At the same time, Assurance approval should focus on demonstrated institutional capability rather than prescribe a single organizational model. Institutions vary substantially in size, research portfolio, governance structure, and access to internal expertise. NIH should define the minimum functions and authorities that must be present while permitting institutions to use shared services, qualified external expertise, consortium arrangements, and externally administered IBCs where those models provide the necessary capabilities.

Where an external or shared IBC is used, written arrangements should distinguish functions that may be performed centrally from responsibilities that require local authority, knowledge, or physical presence. These include access to facility and personnel information, inspections, local training, occupational-health coordination, incident response, urgent safety action, records, implementation of approval conditions, and enforcement.

NIH should also clarify how an institution's Assurance applies to affiliated hospitals, separately incorporated institutes, joint ventures, incubators, leased laboratories, shared core facilities, and other arrangements in which legal ownership, research sponsorship, laboratory location, personnel, and operational control do not fall within the same organizational boundary.

IBCs Were Given More Responsibilities, Not More Authority

One of the stated goals of modernization was to strengthen local biosafety oversight. However, the draft primarily increases IBC responsibilities without substantially expanding IBC authority.

The policy places significant new obligations on IBCs, including expanded protocol review, incident review, public posting of meeting minutes and incident reports, review of lower-risk incidents, maintenance of public records, and coordination of NIH approval requests. At the same time, the policy does not:

- Provide explicit enforcement authority;
- Establish mechanisms for suspending unsafe research;
- Create accreditation or certification standards;
- Provide enhanced institutional protections or independence;
- Develop standardized national training resources; or
- Provide additional funding to support these expanded responsibilities.

As written, IBCs appear to assume substantially greater workload without receiving corresponding increases in authority, resources, or institutional standing.

BSOs Remain Underdeveloped Despite Expanded Reliance on Risk Assessment

The draft repeatedly emphasizes risk assessment as the cornerstone of oversight, yet devotes relatively limited attention to the qualifications, authority, and role of BSOs.

The policy assigns BSOs responsibilities such as inspections, incident response, reporting concerns, and

technical consultation. However, it does not establish:

- Minimum qualifications;
- Competency requirements;
- Continuing education expectations;
- Certification standards;
- Staffing expectations;
- Reporting independence;
- Stop-work authority;
- Formal authority to require corrective actions; or
- Required participation in protocol approvals or incident determinations.

Further, institutions without a designated BSO may simply assign these responsibilities to another institutional official, raising questions regarding qualifications, consistency, and independence.

If NIH intends risk assessment to become the central principle of biosafety oversight, BSOs must be strengthened commensurately through national competency expectations, clearly defined authority, organizational independence, and direct access to senior institutional leadership. Assigning additional responsibilities without requiring corresponding institutional standing or authority perpetuates the very structural weakness that the modernization initiative was expected to address. NIH should establish a functional expectation that the senior biosafety official occupy a position with sufficient authority and executive access to implement institution-wide requirements, require corrective action, and elevate unresolved risks without institutional interference.

BSO appointment requirements conflict with mandatory BSO duties

A BSO must be appointed only when the institution conducts BSL-3/4 or GDMO research. If no BSO is designated, another official must perform the listed BSO responsibilities.

Inconsistency: The policy formally conditions the BSO position on certain work, but effectively requires every covered institution to assign the BSO functions to someone. It is unclear whether that alternate official must have equivalent qualifications, independence, access, authority, or institutional standing.

BSO responsibility is defined, but BSO authority is not

The BSO is responsible for inspections, reporting significant problems, incident investigation, and technical advice. The policy does not provide corresponding authority to access facilities and records, stop unsafe work, require corrective action, or elevate unresolved concerns directly to institutional leadership.

This is not simply an omission. It creates an accountability mismatch: the BSO may be held responsible for functions that the policy does not empower the BSO to carry out.

Occupational-health obligations are optional at the institutional level but operationally assigned to the PI

The institution “may” be required to establish an OHSP under other requirements or based on the research. The PI must inform staff of occupational-health or exposure-response procedures that are “advised or required.”

Inconsistency: The policy gives no trigger for when an OHSP is required under this policy, who determines that it is needed, or who develops the procedures that the PI must explain. The influenza provision later expressly requires an occupational health plan for certain work, demonstrating that the policy can provide a trigger when intended.

Facility responsibility is assigned to the PI even when facilities are institutionally managed

The PI must ensure the “integrity, maintenance, and correct functioning” of facilities, physical containment equipment, and PPE. The institution and BSO also carry programmatic and inspection

responsibilities.
Conflict: A PI may control use of equipment and reporting of defects but not building ventilation, certification contracts, capital repairs, emergency power, or institutional maintenance systems. The policy should divide responsibility among the institution, facilities owner, BSO, PI, and equipment user.
Increased Federal Involvement Appears Inconsistent with Calls for Stronger Local Oversight
Many stakeholders supported modernization because it promised a more adaptive, risk-based framework grounded in local expertise. Instead, several provisions create new NIH approval pathways involving:
• Emerging agents;
• Novel agents;
• Certain zoonotic agents;
• Containment reduction requests;
• Certain gene-drive-related activities; and
• Other cases where containment classifications are not readily established.
This creates a fundamental tension within the proposal. The policy repeatedly emphasizes the importance of institutional risk assessment while simultaneously reserving some of the most complex and consequential risk determinations for NIH review.
NIH should carefully evaluate whether these new federal review mechanisms provide sufficient additional safety benefit to justify increased review timelines, duplicated effort, and administrative burden.
The Draft Does Not Clearly Demonstrate a Reduction in Administrative Burden for Low-Risk Research
One of the primary objectives stated throughout the modernization effort was to expand oversight of higher-risk activities while simultaneously reducing unnecessary burden for low-risk research. The draft successfully broadens oversight to include many biological hazards beyond recombinant and synthetic nucleic acid technologies; however, it is less clear how the proposal reduces burden for lower-risk activities.
Several provisions may actually increase review and documentation requirements for activities historically considered low risk, including:
• Certain RG1 genetically modified organisms (e.g., commercially available ABSL-1 mice/rats);
• Transgenic organisms maintained at ABSL-1 or BSL-1;
• Certain plasmids and viral vectors;
• Well-characterized cell lines;
• Lower-risk incident reporting; and
• Expanded delegated-review documentation requirements.
At many institutions, commercially available transgenic mouse strains maintained under ABSL-1 conditions may number in the hundreds, and low-risk plasmids, routine cloning constructs, and well-characterized cell culture systems represent some of the most common research activities conducted in biomedical laboratories.
Additionally, the proposal creates new documentation, transparency, reporting, and public-record obligations that may increase administrative workload at all levels of oversight. NIH should more clearly demonstrate how the proposed framework achieves its stated goal of reducing administrative burden for low-risk activities and should consider additional exemptions, registrations, or administrative-review pathways where biosafety risk is well understood and minimal.
Delegated Review Is Not a Replacement for Exemption

Throughout the biosafety modernization initiative, NIH discussed preserving proportionate oversight mechanisms for routine, well-characterized, lower-risk research. Historically, some research activities have been exempt from NIH Guidelines registration requirements or allowed to proceed through streamlined notification pathways. Under the proposed Policy, many of these activities would instead require prospective delegated review and approval. Delegated review may be less burdensome than full committee review, but it remains a formal review and approval process.

For example, research involving commercially available ABSL-1 transgenic rodents, certain routine plasmids, specified low-risk viral vectors, genetically modified RG1 organisms, and well-characterized cell lines may require review before initiation despite presenting risks that are already well understood and routinely managed. Institutions would need to identify these activities, evaluate applicability, conduct review, document determinations, communicate approvals, track amendments, maintain records, and report delegated approvals to the IBC.

As a result, the proposal may shift substantial volumes of routine research from exemption or notification pathways into approval pathways. NIH should provide data demonstrating that the additional review creates a meaningful safety, accountability, or learning benefit and should consider whether notification, registration, or exemption pathways remain appropriate for categories of research with well-established risks and control measures.

NIH approval may be required for a very broad, potentially unintended group of unclassified agents

Conflicting provisions: IBCs must petition NIH for emerging, novel, or zoonotic biological agents when an RG classification or containment level is unavailable in the BMBL. Section IV-1 similarly requires NIH and IBC approval for such agents. At the same time, the policy says absence from the RG lists does not imply RG1 and requires an institutional risk assessment.

Why it matters: Many ordinary RG2 agents may lack an explicit BMBL agent summary or minimum containment recommendation. The text could therefore require NIH approval for routine work, even when the agent is not meaningfully “emerging,” “novel,” or “zoonotic.”

Technical Comments

Sections IV-2 and IV-3 overlap without a precedence rule.

Conflicting provisions: Section IV-2 requires full IBC review for genetically modified cells, viruses, or organisms other than plants, apparently across all risk groups. Section IV-3 permits delegated review for genetically modified RG1 agents, transgenic organisms at BSL-1/ABSL-1, certain plasmids and viral vectors, and well-characterized cell lines.

Why it matters: The same submission may qualify simultaneously for full-committee and delegated review. “Not otherwise specified in other sections” may be intended as a carve-out, but the policy never expressly says IV-3 controls over IV-2.

Delegated approval is both delegated and effectively submitted to the full committee record

Delegated reviewers may approve lower-risk work, but every approval must be reported “in full” to the IBC at its next meeting and included in the minutes. Those minutes must then be publicly posted.

Internal policy tension: Delegated review is presented as streamlining, yet it creates mandatory full reporting, minute documentation, approval of those minutes, redaction review, and public posting. The policy does not say whether the full IBC merely receives the approval or can reconsider it.

“Well-characterized cell lines” are assigned delegated review without a clear scope basis

The scope applies to cells or organisms containing covered agents or modifications, but Section IV-3 separately lists research with well-characterized cell lines.

Unclear result: A non-recombinant, well-characterized human cell line may be included under IV-3 even

when it is not known to contain a pathogen and does not independently satisfy the scope definition. Conversely, Section IV-2 requires full IBC review of primary cells that "may" contain adventitious agents. The policy needs explicit criteria distinguishing exempt cell culture, delegated review, and full review.

"Initial submissions" and "de novo" review requirements do not align cleanly

Section IV-2 says initial submissions within scope generally require IBC review. Section III-B permits approvals for no more than three years and then requires a de novo registration and review.

Unresolved question: Is a three-year de novo renewal treated as an "initial submission," thereby defaulting to full IBC review even when the research would otherwise qualify for delegated review under IV-3? The policy should expressly state whether renewal follows the same review pathway as the underlying risk category.

Continuing-Oversight Requirements Are Not Functionally Distinguished

The draft establishes multiple forms of continuing oversight, including de novo review, periodic review, inspections, modification review, incident-driven reassessment, and NIH containment determinations, but does not clearly define the distinct purpose of each activity or how information generated through one process may satisfy another. Without such distinctions, periodic review may become a second abbreviated protocol review, de novo review may repeat information already verified through inspections and modification review, and minor inspection findings or incidents may unnecessarily reopen an entire protocol.

NIH should publish a continuing-oversight matrix identifying the purpose, trigger, responsible party, minimum documentation, relationship to the existing approval period, and effect on research authorization for each process. Institutions should be permitted to reuse or verify unchanged information and to rely on findings generated through another oversight activity when those findings address the same question.

NIH should also explain the basis for applying the same three-year maximum approval period to lower-risk delegated research and higher-risk full-committee research. A predictable national minimum may be appropriate, but the incremental value and necessary depth of reassessment may differ by risk, uncertainty, research stability, inspection history, and other continuing-oversight information.

NIH determinations are described as both project-specific and generally published precedents

IBC petitions must contain experiment-specific details, including modifications, biological systems, manipulations, reagents, animal work, local containment, and the institution's risk assessment. NIH then publishes approved determinations for lower-containment research.

Unresolved issue: It is unclear whether a published NIH determination:

- applies nationally to equivalent work;
- is limited to the requesting institution;
- is limited to the named PI, facility, construct, or procedure; or
- may be relied upon by a different IBC without another NIH petition.

This directly affects whether the approval system becomes a reusable national resource or a series of duplicative case-by-case requests.

"Initial requests" implies precedent, but reliance on prior determinations is not defined

NIH reviews initial requests to lower containment for RG3/RG4 work, while full IBC review applies when NIH previously approved such work at lower containment.

The proposal implies that subsequent requests may not require new NIH review, but it never defines "previously approved," substantial equivalence, acceptable deviations, or who determines that a prior decision applies.

3. Continued utility of Risk Groups: Risk Groups remain a useful and important tool for hazard communication, institutional review, and initial characterization of biological risk. They provide a common language for communicating hazard characteristics across institutions and agencies. While Risk Groups do not fully account for experimental context, manipulations, or mitigation strategies and should not independently dictate containment or oversight decisions, they remain an effective starting point when used with agent-specific and experiment-specific risk evaluation. Institutional risk assessment should remain the foundation for determining appropriate containment and other biosafety controls.

Mandatory Requirements and Advisory Technical Guidance Must Be Distinguished

The final Policy should also clearly distinguish mandatory NIH requirements from advisory technical recommendations in the BMBL. Although the BMBL appropriately serves as a primary technical resource for protocol-specific risk assessment, it does not independently establish federal jurisdiction, institutional review requirements, or enforceable compliance obligations. Institutions therefore need to know which practices are mandatory under the Policy, which are recommended starting points, when equivalent or alternative controls may be used based on a documented risk assessment, and what documentation is expected when professional biosafety judgment supports an approach that differs from a BMBL recommendation.

Without a clear distinction, institutions may treat advisory recommendations as mandatory requirements or, conversely, may apply institutional discretion where NIH intended a binding minimum. This ambiguity directly affects containment determinations, Assurance review, and what NIH will consider noncompliance.

Lack of Training Infrastructure

The policy heavily relies on investigator, BSO, and IBC risk assessments but provides little guidance regarding how competency will be achieved or maintained.

The policy requires training but does not establish:

- National training curricula;
- Core competencies;
- Risk assessment certification programs;
- Standardized case studies;
- Continuing education requirements; or
- Federal training resources.

Modernization should include a national framework for biosafety and biorisk management training to improve consistency across institutions. This competency infrastructure should complement, rather than replace, clear assignment of institutional and investigator training responsibilities.

“Genetic modification” is expansive enough to capture conventional selection and non-biological hazard programs

The definition includes stable alterations produced through passaging, reassortment, chemical means, or radiological means.

This creates several internal tensions:

- The policy is framed as biosafety oversight of biohazards, but the definition may capture organisms altered through chemical mutagenesis or irradiation.
- Genetically modified RG1 agents require delegated review, even if the modification does not plausibly increase risk.
- An organism selected through passage could be regulated as genetically modified even without recombinant or synthetic nucleic acid manipulation.

• The definition may turn attenuation by passage into “genetic modification,” while the wild-type definition excludes organisms with deliberately introduced modifications.
Suggested correction: Distinguish deliberate genetic engineering from selection, adaptation, reassortment, induced mutagenesis, and incidental genomic change, then assign oversight based on the resulting risk rather than treating every category identically.
Mandatory BSL-2 for all GDMOs conflicts with risk-based environmental containment
All GDMOs must be conducted at a minimum of BSL-2, while the policy later recognizes geographically, environmentally, and genetically isolated settings as possible containment strategies.
This is difficult to reconcile for non-microbial organisms managed in specialized arthropod, aquatic, greenhouse, or ecological containment facilities that do not neatly map to BSL-2 laboratory design.
Influenza containment language is overbroad or grammatically ambiguous
The policy states that experiments with viruses containing genes or segments from specified strains must be conducted at BSL-3 enhanced containment. The wording does not establish whether this applies to:
• any segment;
• only segments associated with increased risk;
• a majority of the genome;
• infectious virus versus non-replicating constructs; or
• low-pathogenicity strains that share an H5 subtype but are not within the specified highly pathogenic lineage.
This is especially inconsistent with the preceding influenza rule, which uses the source of the majority of segments to determine containment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The value of voluntary adoption will depend on whether the framework is practical, scalable, understandable, and supported by sufficient resources. Institutions not legally subject to the Policy are unlikely to adopt a system that requires extensive prospective review of routine low-risk research, detailed public posting, complex incident classification, and substantial administrative infrastructure without a clear safety benefit.

NIH should allow voluntary adopters to implement the Policy through a scalable, risk-based model. Core principles and minimum program capabilities could remain consistent, while review pathways, staffing models, documentation, and governance structures are proportionate to the institution’s research portfolio. Shared or consortium IBCs, externally administered review, external biosafety expertise, mutual-aid arrangements, and standardized national tools may be especially important for smaller institutions.

Voluntary compliance would also be more attractive if NIH preserved registration, notification, and exemption pathways for predictable low-risk research rather than requiring formal approval of every covered activity. Requiring every delegated approval to be reported in full and incorporated into publicly posted minutes may discourage adoption by institutions that lack dedicated biosafety administrative personnel.

NIH should provide model policies, Assurance materials, risk-assessment tools, scope and review decision trees, standardized training, examples, shared databases, and technical-assistance resources that voluntary adopters can use without developing complete systems independently. NIH should also

consider recognition mechanisms and implementation support for institutions that voluntarily adopt the framework.

Public-disclosure requirements should be carefully calibrated. Voluntary adoption is less likely if institutions conclude that participation will require extensive disclosure of investigator identities, research details, incidents, or security-sensitive information beyond what is necessary for accountability. Standardized, de-identified public summaries and aggregate reporting would be more compatible with voluntary adoption while preserving transparency and safety learning.

Finally, NIH should distinguish voluntary compliance with the Policy from voluntary submission of near misses or other information to NBDSAC. Institutions need clear confidentiality, de-identification, access, disclosure, and non-enforcement protections before they will participate confidently in a voluntary national learning system.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: NIH should consider whether overly burdensome public-reporting requirements could discourage voluntary adoption of the framework by institutions not otherwise subject to the policy. Voluntary adoption is more likely when requirements are practical, scalable, and supported by clear guidance and shared resources. Encouraging voluntary compliance will require balancing transparency and accountability with implementation burden, confidentiality, and the need to preserve a strong reporting culture.
Public posting obligations conflict with privacy and de-identification principles.
Conflicting provisions: Institutions must post detailed IBC minutes and all incident reports publicly, subject to unspecified “appropriate and allowable” redactions. The policy separately requires NBDSAC data to be de-identified and protects voluntarily reported institutional and individual privacy.
Why it matters: The policy applies a clear de-identification standard to voluntary federal reporting but no corresponding standard to mandatory public posting. Without defined allowable redactions, institutions may either disclose too much or redact inconsistently.
Recused members may count toward quorum
The policy bars members from reviewing or approving projects in which they have a conflict, but permits them to count toward the voting quorum even when recused from the final determination.
Governance inconsistency: A quorum is ordinarily intended to ensure that a sufficient number of eligible members can deliberate and vote. Counting an ineligible member could permit approval by fewer non-conflicted members than the nominal quorum requirement suggests. The policy also does not specify the vote denominator after recusal.
Training is required but no minimum standard or responsible training authority is established
Separate from the national competency infrastructure discussed above, the policy does not clearly allocate responsibility for delivering, documenting, and verifying required training. The institution must ensure training for IBC members, BSOs, PIs, and laboratory staff, while the PI must provide or coordinate training for personnel. The policy also requires posting synopses of relevant staff training, but does not define required content, frequency, competency assessment, NIH-provided training, or documentation standards.
Result: Institutions and PIs have overlapping accountability, while neither has a defined compliance benchmark.
Assurance approval is a prerequisite, but the policy provides no transition mechanism
No covered research may be conducted until NIH approves the institution’s written Biosafety Assurance.

The policy applies to all existing awards and ongoing intramural studies six months after publication of the final policy. Assurances may be approved for up to four years.
Operational inconsistency: If NIH has not approved every recipient's assurance by the effective date, the literal text appears to halt ongoing covered research. The draft does not provide provisional assurances, deemed approval, phased implementation, or continued operation while an assurance is under review.
Record-retention periods are not mapped to record types
The policy cites a three-year federal award-record period but separately requires public posting of IBC minutes and incident reports for at least five years. It says some records may need longer retention and that records associated with awards must remain publicly available during the applicable period. It does not state the retention period for protocols, risk assessments, delegated reviews, training documentation, determinations, or assurance records.
Needed correction: A record-retention table identifying the triggering event, retention period, public-posting period, responsible custodian, and treatment of records covering multiple awards.
Incident-reporting categories overlap
Reportable categories include:
• any BSL-3/ABSL-3 or BSL-4/ABSL-4 incident;
• potential exposures involving injury or medical treatment;
• BSL-2/ABSL-2 exposures requiring agent-specific treatment;
• compliance violations at any level;
• lower-risk BSL-1/2 incidents that remain internally reportable; and
• minor spills that generally do not need reporting.
Ambiguities:
• "Any incident" at high containment is broader than the examples that follow it.
• "Basic first aid" and "agent-specific treatment" are not defined.
• A minor spill may be excluded, while another provision captures any BSL-1/2 incident.
• An animal bite or scratch must be reported to the IBC even without biohazard exposure, provided it occurred during research subject to the policy.
• A compliance violation may be reportable to NIH even if it presented no actual safety risk.
Incident Reporting Must Account for Preliminary and Evolving Information
Institutions may be required to classify an incident before medical, engineering, or investigative facts are complete. NIH should therefore define the minimum information required for the initial 24-hour notification and make clear that this notification is preliminary and need not include a completed root-cause analysis, final medical findings, or completed corrective actions. Institutions should be permitted to identify unresolved matters in the 30-day report, provide material updates as additional information becomes available, and reclassify an event in good faith as the facts develop.
NIH should also clarify how precautionary medical evaluation, diagnostic testing, observation, prophylaxis, and later medical findings affect the reporting determination. Medical consultation or prophylaxis may be provided out of an abundance of caution before the significance of an exposure is known and should not automatically determine the final incident classification.
When one event is reportable under multiple federal programs, NIH should permit a common factual investigation and core report, supplemented only by program-specific information. Federal systems should use a common event identifier or another reconciliation mechanism so that one underlying event is not treated as multiple incidents solely because it is reported to more than one program.
Public reporting may undermine the voluntary near-miss program

Lower-risk incidents must be reported internally, finalized, and publicly posted. Near-misses may also be voluntarily and confidentially submitted to NBDSAC, whose data must be de-identified.
Policy-design conflict: The federal system is designed around confidentiality and de-identification, while the institutional system requires public reports. The boundary between a mandatory "lower-risk incident" and a voluntary "near-miss, secondary failure, or procedural issue" is not defined.
The policy refers to NIH's "final response" without a response deadline
Institutions must post reportable incident information within 30 days of NIH's final response, and NIH must review and respond "in a timely manner." No defined deadline or endpoint establishes when NIH's response is final.
Result: Institutions cannot control or predict the public-posting date, and an open-ended NIH review could leave a report in provisional status indefinitely.

6. Other feedback relevant to this resource: Major Comments
Six-Month Implementation Timeline Is Unrealistic
The policy becomes effective six months after publication of the final version and appears to require approved Biosafety Assurances before research may continue.
Even institutions with mature biosafety programs will likely need to:
• Revise policies and procedures;
• Develop assurance processes;
• Build new public web infrastructure;
• Create redaction procedures;
• Modify protocol management systems;
• Develop new training materials;
• Expand protocol inventories;
• Train investigators, IBC members, and biosafety staff; and
• Establish new incident reporting workflows.
For smaller universities, hospitals, teaching institutions, and emerging research organizations, these changes may require substantial new staffing and infrastructure investments. Although NIH has issued draft templates for incident reporting and IBC meeting minutes, institutions do not yet have the full set of training resources, databases, guidance documents, risk assessment tools, assurance materials, and implementation resources needed to support this transition.
NIH should provide a minimum 24-month phased implementation period following publication of the final Policy and the foundational implementation materials necessary for compliance. Implementation milestones should be tied to the availability of final definitions, decision tools, templates, Assurance instructions, reporting systems, training materials, redaction standards, and NIH review capacity, rather than running solely from publication of the final Policy. If those materials are delayed, NIH should use defined conversion periods, grandfathering, provisional or deemed Assurance mechanisms, and other transition measures so that institutions do not lose usable implementation time or have to suspend otherwise compliant research.
NIH Should Establish Federal Review Service Standards
The draft assigns institutions numerous fixed deadlines and makes some research activities dependent on prior NIH action, but it does not establish corresponding operational expectations for federal review. NIH should publish service standards for Biosafety Assurance review, containment determinations, incident follow-up requiring federal direction, and other decisions that may delay institutional action. These standards should address submission completeness, expected review timeframes, requests for

additional information, pause-and-restart rules, written decisions, escalation pathways for delayed reviews, and the status of research when a complete and timely submission remains pending through no fault of the institution. NIH should also establish continuity procedures for a lapse in federal appropriations, government closure, system outage, or other period during which NIH is unable to act. Institutions should not be required to suspend otherwise compliant research or incur a compliance finding solely because a federal administrative review remains incomplete or NIH systems are unavailable.

NIH Should Establish a National Biosafety Determination and Risk Classification Database

The draft policy creates multiple mechanisms through which NIH may make determinations regarding containment levels, risk classifications, and lower-containment approvals. However, the policy does not describe how these determinations will be communicated to the broader research community or whether previously issued determinations may be relied upon by other institutions.

Without a centralized system, institutions may be required to repeatedly submit similar requests regarding the same organisms, experimental systems, or containment questions, resulting in duplicative effort both for institutions and NIH. This concern is particularly relevant for novel, emerging, zoonotic, or poorly characterized biological agents, where local institutions may lack access to prior federal determinations.

NIH should establish and maintain a publicly searchable database similar to Health Canada's ePathogen system that includes:

- Risk Group classifications;
- NIH containment determinations;
- Approved lower-containment decisions;
- Agent summaries;
- Relevant precedent decisions; and
- Associated guidance documents.

Such a resource would improve consistency, reduce duplication, increase transparency, and support risk-based decision making across the research enterprise.

Standardized Templates and Implementation Resources Require Further Development Prior to Implementation

The draft policy appropriately recognizes the importance of implementation support and NIH has already taken an encouraging first step by publishing draft templates for both incident reporting and IBC meeting minutes. Standardized forms have the potential to improve consistency across institutions and promote transparency regarding biosafety oversight activities.

NIH should clarify whether its templates are mandatory, recommended, or illustrative. Compliance should be based primarily on required content and performance standards rather than use of a particular document format. Many institutions already use electronic compliance-management systems that generate agendas, attendance records, voting outcomes, protocol summaries, approvals, and meeting records from structured data. Institutions should be permitted to continue using those systems and alternative formats when all required information is captured, retained, and made publicly available as required.

A minimum-content approach would promote consistency while avoiding unnecessary system modifications or manual duplication of information already maintained in institutional records. NIH should distinguish clearly between required data elements and model templates intended to assist institutions.

The current draft templates raise significant implementation concerns that should be resolved prior to policy implementation. The draft IBC meeting minutes template requires substantial documentation of protocol summaries, risk assessments, training, occupational health considerations, biosafety level determinations, committee discussions, delegated review activities, incidents, inspections, and other committee business. Similarly, the incident reporting template requires extensive documentation regarding personnel, training history, SOP compliance, occupational health considerations, corrective actions, and root cause analysis.

While transparency is an important objective, the level of detail contemplated by these templates may create substantial administrative burden for institutions and IBCs. In particular:

• The meeting-minutes template appears to require documentation of a significant portion of the committee's deliberative process and risk assessment rationale.

• The meeting-minutes template requires documentation of delegated-review approvals within publicly posted minutes, potentially reducing some of the efficiency benefits of delegated review.

• Both templates require public disclosure of information that may traditionally have been retained within institutional records rather than prepared for public consumption.

• The incident-reporting template expressly states that PI names, biological agents, grant numbers, and other information commonly available from public sources may not be redacted. While intended to increase transparency, this approach may have unintended consequences for reporting culture, personnel safety, and research security. Publicly associating named investigators and identifiable research personnel with specific biological agents, animal studies, facilities, or incidents could facilitate harassment, intimidation, targeted activism, or other threats, particularly in connection with controversial or sensitive research. The potential risks extend beyond PIs to animal care personnel, veterinarians, biosafety professionals, laboratory staff, and other employees associated with the work. The draft provides de-identification and privacy protections for information submitted to the National Biosafety Data and Safety Analysis Center but does not establish a comparable risk-based framework for publicly posted institutional incident reports. NIH should establish clear standards permitting information to be redacted when disclosure could reasonably create personnel-safety, research-security, privacy, or harassment concerns without materially advancing transparency or public-health objectives.

• The draft policy and templates do not clearly define the boundaries of allowable redaction practices, leaving institutions vulnerable to inconsistent implementation and potential disputes regarding appropriate public disclosure.

In addition, several key implementation resources are still absent. Institutions will need additional guidance and standardized tools to ensure consistent implementation, including:

• Biosafety Assurance templates;

• Comprehensive risk assessment templates and examples;

• Example completed incident reports and meeting minutes;

• Training materials for IBC members, BSOs, Investigators, and Institutional Officials;

• Guidance documents describing acceptable implementation approaches for institutions of varying size and complexity;

• Clear redaction guidance for public meeting minutes and incident reports;

• National databases for containment determinations and Risk Group classifications;

• Guidance regarding what qualifies for delegated review versus full committee review; and

• Interagency guidance clarifying relationships among NIH, USDA, CDC, FDA, EPA, OSHA, and Select Agent requirements

NIH should pilot test the proposed templates with institutions representing a range of biosafety program sizes and maturity levels before finalizing these requirements. Feedback from such pilots would help ensure that transparency objectives are achieved without creating unnecessary administrative burden or inadvertently discouraging incident reporting. Further refinement of these templates and supporting implementation resources would likely improve both consistency and long-term compliance outcomes. Institutions should be afforded an opportunity to review draft implementation materials before final policy implementation because several critical operational details appear to depend on future guidance rather than the policy text itself.

Material Revisions and Implementation Requirements Should Receive Stakeholder Review

Because several critical requirements remain undefined and may be resolved through later guidance, templates, or substantial revisions to the Policy, NIH should provide stakeholders an opportunity to review and comment on materially revised policy language and major implementation materials before they become binding. At a minimum, institutions should be able to evaluate the complete package of scope definitions, review criteria, Assurance requirements, reporting standards, public-disclosure rules, and transition procedures before implementation obligations are finalized.

Modernization Should Not Become an Unfunded Mandate

The draft policy substantially expands biosafety oversight responsibilities, increases transparency requirements, establishes new reporting obligations, and requires expanded institutional infrastructure. However, the policy does not identify corresponding funding mechanisms to support these activities. Implementation of the proposed requirements will likely require:

- Additional biosafety personnel;
- Expanded administrative support;
- Information technology infrastructure;
- Public reporting systems;
- Training development;
- Increased protocol management capacity; and
- Enhanced institutional oversight activities.

For many institutions, particularly smaller institutions, teaching-focused universities, hospitals, and emerging research organizations, these activities may represent substantial new costs.

NIH should consider mechanisms to support implementation, including:

- Dedicated biosafety supplements;
- Allowable Facilities and Administrative (F&A) recovery for biosafety activities;
- Workforce development initiatives;
- National training programs; and
- Shared implementation resources.

Expanding oversight without corresponding support may create significant implementation challenges and increase disparities between large and small institutions.

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NIH Draft Policy Comments

Input on Draft NIH Biosafety Policy for Research Involving Biohazards – Individual Perspective

This letter represents my individual professional perspective based on my experience as a biosafety professional and does not necessarily represent the official position or policy of my employer. Any views, opinions, or recommendations expressed herein are my own and should not be construed as reflecting the institutional stance of my employer or its administration.

I appreciate NIH's commitment to modernizing biosafety oversight through a broader risk-based framework that reflects the realities of contemporary biological research. The draft policy successfully expands oversight beyond recombinant and synthetic nucleic acid technologies and addresses several longstanding gaps in biosafety oversight. At the same time, the draft raises important questions regarding scope, risk categorization, institutional authority, implementation feasibility, transparency, and administrative burden. The comments below are organized around the specific topics identified by NIH in the Request for Information and are intended to support the development of a practical, effective, and sustainable oversight framework.

The policy also increases transparency through public posting of Institutional Biosafety Committee (IBC) rosters, meeting minutes, incident reports, and publication of NIH incident summaries. While transparency is an important objective, several provisions may inadvertently discourage institutional reporting and limit the willingness of researchers to voluntarily share near misses and lessons learned.

However, the draft falls short of several key objectives discussed throughout the modernization effort. A recurring theme expressed during stakeholder engagement was the need to strengthen local biosafety oversight programs by empowering Institutional Biosafety Committees and Biological Safety Officers, providing standardized training and risk-assessment resources, expanding institutional authority to make risk-based decisions, and improving coordination among federal agencies.

Most significantly, the draft does not deliver on the modernization initiative’s stated objective of strengthening IBCs and moving biosafety oversight toward institutional parity with IRBs and IACUCs. Instead, it substantially increases institutional responsibilities, reporting requirements, documentation obligations, administrative workload, and compliance expectations while providing few additional authorities, resources, implementation tools, or institutional support mechanisms. It expands what IBCs and BSOs must do, but does not establish corresponding expectations for institutional standing, independence, executive access, authority, staffing, or resources. In several areas, authority appears to move away from local biosafety expertise and toward NIH review and approval processes. As a result, the policy expands oversight without proportionally strengthening the institutional infrastructure responsible for implementing that oversight. This is not a secondary implementation issue; it is a fundamental structural omission that threatens the effectiveness of the entire proposed framework.

The result is a framework that increases compliance obligations but does not fully address long-standing concerns regarding:

- IBC authority and institutional support;
- BSO qualifications, authority, independence, and staffing;
- Standardized biosafety and risk assessment training;
- National risk assessment resources and tools;
- Federal agency harmonization;
- Gaps in plant, agricultural, and environmental-risk oversight;

- The effects of mandatory public disclosure on reporting culture, privacy, personnel safety, and research security;
- Sustainable funding mechanisms for expanded oversight; and
- Implementation feasibility across institutions of varying size and maturity.

The comments below identify areas where the draft policy successfully advances the goals of biosafety modernization, as well as specific examples where it may not fully achieve the objectives discussed during stakeholder engagement. In addition, the comments highlight inconsistencies, ambiguities, definitional gaps, and potential implementation challenges that could affect clarity, consistency, and effective institutional adoption of the policy.

1. Scope of Research Covered by the Policy

Major Comments

Positive Aspects of the Draft Policy

The draft advances several important modernization goals by:

- Expanding oversight beyond recombinant and synthetic nucleic acid methodologies;
- Bringing wild-type biological agents into the oversight framework;
- Recognizing emerging technologies and novel biological risks;
- Attempting to establish more structured incident-reporting categories and timelines;
- Increasing transparency; and
- Acknowledging the need for implementation resources.

Need for Greater Interagency Harmonization

The draft frequently references other federal agencies but does not establish mechanisms for resolving overlapping jurisdictional questions or conflicting regulatory interpretations. This is particularly concerning given the continued ambiguity surrounding:

- Plant pathogens;
- Animal pathogens;
- USDA-regulated activities;
- FDA-regulated clinical activities;
- Select Agent programs; and
- Environmental release activities.

Without stronger coordination mechanisms, institutions may continue to face fragmented and inconsistent oversight requirements.

The modernization initiative appropriately seeks to broaden oversight beyond traditional recombinant DNA frameworks. However, several definitions and concepts appear to differ from terminology already used by NIH, USDA, CDC, EPA, and other federal agencies.

Examples include terminology related to:

- Novel organisms;
- Genetically engineered organisms;
- Animal pathogens;

- Plant pathogens;
- Environmental release; and
- Containment classifications.

Differences in terminology create opportunities for inconsistent interpretation and may increase regulatory burden for institutions conducting research subject to multiple federal oversight frameworks.

NIH should work with partner agencies to harmonize terminology wherever possible and publish joint guidance when differences cannot be avoided. A formal interagency biosafety coordination mechanism would further improve consistency and reduce regulatory confusion.

The Policy Does Not Address Continuity of Large-Scale Biosafety Requirements

Replacing the current NIH Guidelines also raises a significant continuity question for large-scale biosafety. Appendix K currently provides nationally recognized physical-containment and operational practices for large-scale work involving viable organisms containing recombinant or synthetic nucleic acid molecules, and BMBL Appendix M expressly refers to Appendix K as a source of practices applicable to large-scale work involving both genetically modified and non-genetically modified biological materials. The proposed Policy does not state whether Appendix K will remain effective, be incorporated into binding implementation materials, be superseded by BMBL Appendix M, or be replaced by another maintained standard.

This omission could leave institutions, production facilities, and the professionals who evaluate large-scale systems without a clear federal baseline for matters such as closed systems, transfer operations, aerosol generation, inactivation, waste handling, utilities, and process-specific engineering controls. It is also notable that the draft no longer identifies large-scale work as an independent trigger for mandatory appointment of a BSO.

NIH should identify the future status of Appendix K, the applicability of large-scale containment provisions to recombinant, genetically modified, and non-recombinant biological materials, the respective status of mandatory and advisory provisions, the qualifications and institutional expertise expected for large-scale work, and the federal entity responsible for maintaining and updating this guidance.

Other-agency oversight language could be read as either substitution or duplication

The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. It does not say whether NIH-policy oversight is displaced, deemed satisfied, or remains concurrent.

This conflicts with the later statement that clinical research cannot begin until IBC **and all other** institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight.

NIH should adopt a function-specific reliance framework rather than treating another federal program as either wholly substitutive or wholly duplicative. A federal permit, inspection, registration, accreditation, or approval may already establish particular facts concerning facilities, containment features, training, personnel qualifications, permitted activities, or required controls without resolving the entire research-specific biosafety assessment. Institutions should be permitted to incorporate and

rely upon those findings for the questions they actually address while retaining IBC responsibility for experimental features or local conditions not resolved through the other process.

NIH should publish an issue-specific crosswalk identifying potentially overlapping federal programs, the functions that may be satisfied through reliance, the documentation needed to establish reliance, the limits of that reliance, and the responsibilities that remain with the institution or IBC. This would reduce duplicative review without incorrectly treating distinct federal programs as interchangeable.

The Exclusion of Genetically Modified Plants Creates a Significant Regulatory Gap

The draft repeatedly recognizes environmental risk, unintended release, ecological impacts, environmental containment, population-level consequences, and the potential for broader environmental effects arising from biotechnology research. At the same time, genetically modified plants are expressly excluded from the scope of the policy. This exclusion is difficult to reconcile with the policy's stated objectives and risk-assessment framework.

At a minimum, genetically modified plants may present plausible food or feed safety concerns, agricultural impacts, ecological consequences, environmental persistence, gene flow, or other environmental risks that warrant institutional review and risk assessment. The draft requires IBCs to evaluate environmental risks and, in some circumstances, maintain expertise in ecological and environmental risk assessment, yet expressly excludes a major category of research capable of creating agricultural, ecological, food or feed, and other environmental consequences.

More broadly, the plant exclusion illustrates a recurring challenge throughout the draft: the absence of a clearly coordinated federal oversight framework. Federal oversight of biotechnology products is distributed principally among USDA, FDA, and EPA under the Coordinated Framework for the Regulation of Biotechnology. However, product-focused regulatory authorities do not necessarily provide continuous institutional oversight of all contained research activities preceding product development, field testing, environmental release, or commercialization. The draft does not explain whether NIH considers those product-focused authorities sufficient to replace institutional biosafety oversight during the research phase, or how occupational, containment, biosecurity, and environmental risks falling outside a defined regulatory trigger should be addressed.

If NIH intends to exclude plant research because it believes other federal agencies provide sufficient oversight, the policy should explicitly state that rationale and clearly describe where responsibility transfers from institutional biosafety oversight to other regulatory programs. As written, the policy does neither. The result is uncertainty regarding whether plant-related research falls outside oversight entirely, is expected to be reviewed under another federal framework, or remains subject to institutional review through some mechanism not described in the policy.

NIH should either incorporate appropriate oversight of genetically modified plants within the policy's scope or clearly articulate the interaction between NIH requirements and USDA, FDA, and EPA authorities, including the specific circumstances under which institutional biosafety oversight is expected, reduced, or displaced. Without a defined relationship among NIH institutional-oversight requirements and USDA, FDA, and EPA authorities, the exclusion risks creating precisely the type of ambiguity, gap, or inconsistent oversight that federal coordination is intended to prevent.

The plant exclusion is particularly notable because it represents one of the clearest examples where the draft expands discussion of environmental risk while simultaneously excluding a major category of research capable of creating environmental consequences.

Technical Comments

The policy covers "all biohazards," but never defines "biohazard."

Conflicting provisions: The background repeatedly characterizes the proposal as applying to "all biohazards," and the scope defines "research involving biohazards" through a list of covered materials. However, the definitions section contains no definition of biohazard itself.

Why it matters: Institutions cannot reliably determine the boundary of the policy, especially for materials that present environmental, animal, plant, toxicological, or occupational risks without clearly posing a human-health risk.

The scope claims to address environmental risk while largely excluding plant hazards and plant genetic modification.

Conflicting provisions: Scope is limited to risks to human health and excludes genetically modified plants. Yet IBC responsibilities require assessing risk to the environment, policy definitions include environmental considerations, and risk-assessment provisions discuss impacts on populations and the environment.

Why it matters: A genetically modified plant with ecological or agricultural consequences appears outside scope even though the policy requires IBCs to assess environmental risks. This creates a substantive gap rather than merely an editorial issue.

"Biological agent" is defined too narrowly for how the term is used

The policy defines a biological agent as bacteria, viruses, fungi, or parasites that cause human disease. That excludes nonpathogenic organisms, animal-only pathogens, plant pathogens, and agents with uncertain pathogenicity. Yet later provisions repeatedly use "biological agent" when discussing RG1 materials, zoonotic agents, genetically modified agents, environmental impacts, and organisms not currently known to cause human disease.

Suggested correction: Define *biological agent* neutrally, such as bacteria, viruses, fungi, parasites, and other biologically derived or replicating entities. Define *biohazardous biological agent* separately based on the capacity to cause harm.

The expanded-access exemption is narrower than the reasoning appears to support

A single-patient FDA-regulated expanded-access use is excluded because it is not research, but the policy does not address analogous veterinary expanded access, compassionate use, emergency investigational use outside the exact IND terminology, or activities that involve preparation and handling by research laboratories.

The key inconsistency is between a policy scope framed around "research" and operational activities that may carry the same biosafety risks but receive different treatment based on regulatory designation.

Animal hazards are treated inconsistently

The scope covers wild-type agents only when they cause disease in humans, which appears to exclude animal-only pathogens. Nevertheless:

- "Prions and self-aggregating proteins" include materials causing disease in humans **or animals**.
- "Zoonotic" agents are expressly defined.
- IBC membership must include animal-containment expertise under certain circumstances.
- The policy requires reporting incidents involving covered research animals.
- Risk assessment and containment provisions address animal populations and ABSL containment.

Result: The policy regulates animal-related procedures and environmental consequences, but its threshold definition may exclude the underlying animal pathogen unless it is zoonotic or genetically modified.

Toxin scope and toxin oversight do not align

Scope covers "toxins" without an express threshold, but the definition limits toxin to a protein or peptide produced by living organisms that harms humans. Section IV-2 assigns full IBC review to Select Agent toxins, while Section IV-3 permits delegated review for non-Select Agent biological toxin proteins.

Unresolved points include:

- Whether all quantities and concentrations are covered.
- Whether inactive toxin derivatives are covered.
- Whether isolated subunits are "toxins."
- Whether nucleic acids encoding toxins are treated as toxin research, genetic modification, or both.
- Whether low-toxicity proteins technically capable of harm require delegated IBC review.
- Why peptides are included in the definition but IV-3 refers only to "toxin proteins."

This is a major administrative-burden issue because the literal language has no de minimis or potency threshold.

Self-aggregating proteins are treated both as a broad class and as disease-causing materials

The scope covers "prions and other self-aggregating proteins," while the definition appears limited to misfolded proteins that self-propagate and cause neurodegenerative disease. Section IV-2 then appears to require full IBC review for all prions and other self-aggregating proteins.

Inconsistency: The scope language could capture ordinary aggregating proteins, while the definition is narrower and disease-based. The policy should specify whether the category is limited to transmissible or experimentally propagating protein agents associated with disease.

"Biomedical research" is defined partly by institutional funding status rather than scientific content

The definition first refers to research within the NIH mission, but then includes NIH-supported research and non-NIH-funded research conducted at an NIH-funded institution. This blends a scientific definition with the rule establishing policy applicability.

Why inconsistent: Whether work is "biomedical research" should ordinarily turn on the nature or purpose of the work, while whether it is subject to the policy should be addressed in the applicability section. As written, identical research could be "biomedical" at an NIH-funded institution but not at an otherwise comparable non-recipient institution.

"Laboratory research" includes clinical settings, but clinical research is treated as structurally different

The definition says laboratory research includes clinical settings within BSL/ABSL 1–4 containment facilities. Later, the policy acknowledges that clinical settings generally do not conform to laboratory BSLs.

Why inconsistent: Clinical settings are simultaneously included within a BSL-based definition and described as not conforming to BSLs. A separate definition of *clinical research involving biohazards* would avoid forcing clinical activity into a laboratory-containment framework.

RG1 wild-type agents are excluded, but RG1 derivatives and commonplace materials are swept back in

Section IV-3 explicitly says wild-type RG1 agents are not subject to the policy, but delegated review is required for:

- genetically modified RG1 agents;
- transgenic organisms at BSL-1/ABSL-1;
- certain plasmids;
- replication-incompetent, non-integrating viral vectors;
- well-characterized cell lines; and
- non-Select Agent toxins.

This conflicts with the stated goal of removing red tape for low-risk research. The proposal expands mandatory oversight to many routine research materials that may present no greater biosafety risk than excluded wild-type RG1 organisms. The background promises streamlining, but the operative text creates mandatory pre-initiation review and subsequent reporting of delegated approvals to the IBC.

GDMO terminology is used more broadly than the definition supplied

The policy defines *gene drive* but does not separately define **gene drive modified organism (GDMO)**. It variously refers to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Why this matters: BSO appointment, ecological expertise, NIH approval, and minimum BSL-2 containment all turn on whether work qualifies as GDMO research.

2. Structure of Tiered Oversight and Risk-Based Review

The draft repeatedly states NIH intends to strengthen IBCs. However, the proposal primarily expands IBC responsibilities rather than authority, resources, training, accreditation, or institutional support.

Major Comments

The Draft Fails to Establish Institutional Parity for Biosafety Oversight

A central objective of the biosafety modernization initiative was to strengthen the institutional standing of biosafety oversight and move IBCs toward parity with Institutional Review Boards and Institutional Animal Care and Use Committees. Stakeholders repeatedly emphasized that effective biosafety oversight requires more than an expanded scope of review. It requires IBCs to have comparable institutional recognition, independence, authority, resources, and access to senior leadership.

The draft does not accomplish this objective. Although it substantially expands the responsibilities of IBCs, it does not establish the governance structures necessary to elevate them to a position comparable to IRBs and IACUCs. It does not require institutions to:

- Place the IBC within an appropriately senior institutional oversight structure;
- Provide the IBC with direct access to senior research leadership;
- Establish institutional independence or protections for IBC decision-making;
- Provide the IBC with authority to suspend or require modification of unsafe research;
- Define minimum staffing or administrative support;
- Provide resources proportionate to the expanded scope of oversight; or
- Demonstrate that biosafety oversight receives institutional support comparable to human-subject and animal-care oversight.

The same gap applies to the BSO. Responsibility for implementing an institution-wide biosafety program should be accompanied by institutional authority and standing commensurate with that responsibility. The draft assigns substantial duties to the BSO but does not require an organizational position that provides sufficient independence, access to senior leadership, authority to require corrective action, or protection from conflicts created by competing institutional priorities. For institutions with substantial or complex research programs, NIH should require that the senior biosafety official have direct access to executive research leadership and sufficient organizational stature to raise unresolved safety concerns without relying solely on intermediate reporting channels.

This omission is particularly significant because the draft increases institutional accountability, expands the range of research subject to oversight, and makes risk assessment more dependent on local biosafety expertise. A policy cannot meaningfully strengthen IBCs and BSOs while leaving their institutional status, independence, authority, and resourcing almost entirely undefined. Without enforceable expectations for institutional parity and leadership access, the draft risks creating a system in which IBCs and BSOs are accountable for a much broader program but remain structurally subordinate and inadequately empowered.

NIH should revise the policy to establish minimum institutional-governance expectations for biosafety programs, including:

1. Institutional placement and leadership access appropriate to the scope and complexity of the research program;
2. Documented authority for the IBC or BSO to immediately pause activities presenting an imminent safety concern and authority for the IBC to require corrective action, modify approval conditions, or suspend research when necessary;
3. Independence protections for biosafety determinations;

4. Minimum qualifications and competency expectations for the senior BSO;
5. Staffing and administrative-support expectations based on program size and risk;
6. Direct escalation pathways to an identified senior institutional official with authority over the research enterprise, regardless of the title used by the institution; and
7. A requirement that Biosafety Assurances describe how the institution provides its IBC and biosafety program with authority, resources, independence, and institutional support comparable to other major research-oversight functions.

At the same time, Assurance approval should focus on demonstrated institutional capability rather than prescribe a single organizational model. Institutions vary substantially in size, research portfolio, governance structure, and access to internal expertise. NIH should define the minimum functions and authorities that must be present while permitting institutions to use shared services, qualified external expertise, consortium arrangements, and externally administered IBCs where those models provide the necessary capabilities.

Where an external or shared IBC is used, written arrangements should distinguish functions that may be performed centrally from responsibilities that require local authority, knowledge, or physical presence. These include access to facility and personnel information, inspections, local training, occupational-health coordination, incident response, urgent safety action, records, implementation of approval conditions, and enforcement.

NIH should also clarify how an institution's Assurance applies to affiliated hospitals, separately incorporated institutes, joint ventures, incubators, leased laboratories, shared core facilities, and other arrangements in which legal ownership, research sponsorship, laboratory location, personnel, and operational control do not fall within the same organizational boundary.

IBCs Were Given More Responsibilities, Not More Authority

One of the stated goals of modernization was to strengthen local biosafety oversight. However, the draft primarily increases IBC responsibilities without substantially expanding IBC authority.

The policy places significant new obligations on IBCs, including expanded protocol review, incident review, public posting of meeting minutes and incident reports, review of lower-risk incidents, maintenance of public records, and coordination of NIH approval requests. At the same time, the policy does not:

- Provide explicit enforcement authority;
- Establish mechanisms for suspending unsafe research;
- Create accreditation or certification standards;
- Provide enhanced institutional protections or independence;
- Develop standardized national training resources; or
- Provide additional funding to support these expanded responsibilities.

As written, IBCs appear to assume substantially greater workload without receiving corresponding increases in authority, resources, or institutional standing.

BSOs Remain Underdeveloped Despite Expanded Reliance on Risk Assessment

The draft repeatedly emphasizes risk assessment as the cornerstone of oversight, yet devotes relatively limited attention to the qualifications, authority, and role of BSOs.

The policy assigns BSOs responsibilities such as inspections, incident response, reporting concerns, and technical consultation. However, it does not establish:

- Minimum qualifications;
- Competency requirements;
- Continuing education expectations;
- Certification standards;
- Staffing expectations;
- Reporting independence;
- Stop-work authority;
- Formal authority to require corrective actions; or
- Required participation in protocol approvals or incident determinations.

Further, institutions without a designated BSO may simply assign these responsibilities to another institutional official, raising questions regarding qualifications, consistency, and independence.

If NIH intends risk assessment to become the central principle of biosafety oversight, BSOs must be strengthened commensurately through national competency expectations, clearly defined authority, organizational independence, and direct access to senior institutional leadership. Assigning additional responsibilities without requiring corresponding institutional standing or authority perpetuates the very structural weakness that the modernization initiative was expected to address. NIH should establish a functional expectation that the senior biosafety official occupy a position with sufficient authority and executive access to implement institution-wide requirements, require corrective action, and elevate unresolved risks without institutional interference.

BSO appointment requirements conflict with mandatory BSO duties

A BSO must be appointed only when the institution conducts BSL-3/4 or GDMO research. If no BSO is designated, another official must perform the listed BSO responsibilities.

Inconsistency: The policy formally conditions the BSO position on certain work, but effectively requires every covered institution to assign the BSO functions to someone. It is unclear whether that alternate official must have equivalent qualifications, independence, access, authority, or institutional standing.

BSO responsibility is defined, but BSO authority is not

The BSO is responsible for inspections, reporting significant problems, incident investigation, and technical advice. The policy does not provide corresponding authority to access facilities and records, stop unsafe work, require corrective action, or elevate unresolved concerns directly to institutional leadership.

This is not simply an omission. It creates an accountability mismatch: the BSO may be held responsible for functions that the policy does not empower the BSO to carry out.

Occupational-health obligations are optional at the institutional level but operationally assigned to the PI

The institution "may" be required to establish an OHSP under other requirements or based on the research. The PI must inform staff of occupational-health or exposure-response procedures that are "advised or required."

Inconsistency: The policy gives no trigger for when an OHSP is required under this policy, who determines that it is needed, or who develops the procedures that the PI must explain. The influenza provision later expressly requires an occupational health plan for certain work, demonstrating that the policy can provide a trigger when intended.

Facility responsibility is assigned to the PI even when facilities are institutionally managed

The PI must ensure the "integrity, maintenance, and correct functioning" of facilities, physical containment equipment, and PPE. The institution and BSO also carry programmatic and inspection responsibilities.

Conflict: A PI may control use of equipment and reporting of defects but not building ventilation, certification contracts, capital repairs, emergency power, or institutional maintenance systems. The policy should divide responsibility among the institution, facilities owner, BSO, PI, and equipment user.

Increased Federal Involvement Appears Inconsistent with Calls for Stronger Local Oversight

Many stakeholders supported modernization because it promised a more adaptive, risk-based framework grounded in local expertise. Instead, several provisions create new NIH approval pathways involving:

- Emerging agents;
- Novel agents;
- Certain zoonotic agents;
- Containment reduction requests;
- Certain gene-drive-related activities; and
- Other cases where containment classifications are not readily established.

This creates a fundamental tension within the proposal. The policy repeatedly emphasizes the importance of institutional risk assessment while simultaneously reserving some of the most complex and consequential risk determinations for NIH review.

NIH should carefully evaluate whether these new federal review mechanisms provide sufficient additional safety benefit to justify increased review timelines, duplicated effort, and administrative burden.

The Draft Does Not Clearly Demonstrate a Reduction in Administrative Burden for Low-Risk Research

One of the primary objectives stated throughout the modernization effort was to expand oversight of higher-risk activities while simultaneously reducing unnecessary burden for low-risk research. The draft successfully broadens oversight to include many biological hazards beyond recombinant and synthetic nucleic acid technologies; however, it is less clear how the proposal reduces burden for lower-risk activities.

Several provisions may actually increase review and documentation requirements for activities historically considered low risk, including:

- Certain RG1 genetically modified organisms (e.g., commercially available ABSL-1 mice/rats);
- Transgenic organisms maintained at ABSL-1 or BSL-1;
- Certain plasmids and viral vectors;
- Well-characterized cell lines;
- Lower-risk incident reporting; and
- Expanded delegated-review documentation requirements.

At many institutions, commercially available transgenic mouse strains maintained under ABSL-1 conditions may number in the hundreds, and low-risk plasmids, routine cloning constructs, and well-characterized cell culture systems represent some of the most common research activities conducted in biomedical laboratories.

Additionally, the proposal creates new documentation, transparency, reporting, and public-record obligations that may increase administrative workload at all levels of oversight. NIH should more clearly demonstrate how the proposed framework achieves its stated goal of reducing administrative burden for low-risk activities and should consider additional exemptions, registrations, or administrative-review pathways where biosafety risk is well understood and minimal.

Delegated Review Is Not a Replacement for Exemption

Throughout the biosafety modernization initiative, NIH discussed preserving proportionate oversight mechanisms for routine, well-characterized, lower-risk research. Historically, some research activities have been exempt from NIH Guidelines registration requirements or allowed to proceed through streamlined notification pathways. Under the proposed Policy, many of these activities would instead require prospective delegated review and approval. Delegated review may be less burdensome than full committee review, but it remains a formal review and approval process.

For example, research involving commercially available ABSL-1 transgenic rodents, certain routine plasmids, specified low-risk viral vectors, genetically modified RG1 organisms, and well-characterized cell lines may require review before initiation despite presenting risks that are already well understood and routinely managed. Institutions would need to identify these activities, evaluate applicability, conduct review, document determinations, communicate approvals, track amendments, maintain records, and report delegated approvals to the IBC.

As a result, the proposal may shift substantial volumes of routine research from exemption or notification pathways into approval pathways. NIH should provide data demonstrating that the additional review creates a meaningful safety, accountability, or learning benefit and should consider whether notification, registration, or exemption pathways remain appropriate for categories of research with well-established risks and control measures.

NIH approval may be required for a very broad, potentially unintended group of unclassified agents

Conflicting provisions: IBCs must petition NIH for emerging, novel, or zoonotic biological agents when an RG classification or containment level is unavailable in the BMBL. Section IV-1 similarly

requires NIH and IBC approval for such agents. At the same time, the policy says absence from the RG lists does not imply RG1 and requires an institutional risk assessment.

Why it matters: Many ordinary RG2 agents may lack an explicit BMBL agent summary or minimum containment recommendation. The text could therefore require NIH approval for routine work, even when the agent is not meaningfully "emerging," "novel," or "zoonotic."

Technical Comments

Sections IV-2 and IV-3 overlap without a precedence rule.

Conflicting provisions: Section IV-2 requires full IBC review for genetically modified cells, viruses, or organisms other than plants, apparently across all risk groups. Section IV-3 permits delegated review for genetically modified RG1 agents, transgenic organisms at BSL-1/ABSL-1, certain plasmids and viral vectors, and well-characterized cell lines.

Why it matters: The same submission may qualify simultaneously for full-committee and delegated review. "Not otherwise specified in other sections" may be intended as a carve-out, but the policy never expressly says IV-3 controls over IV-2.

Delegated approval is both delegated and effectively submitted to the full committee record

Delegated reviewers may approve lower-risk work, but every approval must be reported "in full" to the IBC at its next meeting and included in the minutes. Those minutes must then be publicly posted.

Internal policy tension: Delegated review is presented as streamlining, yet it creates mandatory full reporting, minute documentation, approval of those minutes, redaction review, and public posting. The policy does not say whether the full IBC merely receives the approval or can reconsider it.

"Well-characterized cell lines" are assigned delegated review without a clear scope basis

The scope applies to cells or organisms containing covered agents or modifications, but Section IV-3 separately lists research with well-characterized cell lines.

Unclear result: A non-recombinant, well-characterized human cell line may be included under IV-3 even when it is not known to contain a pathogen and does not independently satisfy the scope definition. Conversely, Section IV-2 requires full IBC review of primary cells that "may" contain adventitious agents. The policy needs explicit criteria distinguishing exempt cell culture, delegated review, and full review.

"Initial submissions" and "de novo" review requirements do not align cleanly

Section IV-2 says initial submissions within scope generally require IBC review. Section III-B permits approvals for no more than three years and then requires a de novo registration and review.

Unresolved question: Is a three-year de novo renewal treated as an "initial submission," thereby defaulting to full IBC review even when the research would otherwise qualify for delegated review under IV-3? The policy should expressly state whether renewal follows the same review pathway as the underlying risk category.

Continuing-Oversight Requirements Are Not Functionally Distinguished

The draft establishes multiple forms of continuing oversight, including de novo review, periodic review, inspections, modification review, incident-driven reassessment, and NIH containment determinations, but does not clearly define the distinct purpose of each activity or how information generated through one process may satisfy another. Without such distinctions, periodic review may become a second abbreviated protocol review, de novo review may repeat information already verified through inspections and modification review, and minor inspection findings or incidents may unnecessarily reopen an entire protocol.

NIH should publish a continuing-oversight matrix identifying the purpose, trigger, responsible party, minimum documentation, relationship to the existing approval period, and effect on research authorization for each process. Institutions should be permitted to reuse or verify unchanged information and to rely on findings generated through another oversight activity when those findings address the same question.

NIH should also explain the basis for applying the same three-year maximum approval period to lower-risk delegated research and higher-risk full-committee research. A predictable national minimum may be appropriate, but the incremental value and necessary depth of reassessment may differ by risk, uncertainty, research stability, inspection history, and other continuing-oversight information.

NIH determinations are described as both project-specific and generally published precedents

IBC petitions must contain experiment-specific details, including modifications, biological systems, manipulations, reagents, animal work, local containment, and the institution's risk assessment. NIH then publishes approved determinations for lower-containment research.

Unresolved issue: It is unclear whether a published NIH determination:

- applies nationally to equivalent work;
- is limited to the requesting institution;
- is limited to the named PI, facility, construct, or procedure; or
- may be relied upon by a different IBC without another NIH petition.

This directly affects whether the approval system becomes a reusable national resource or a series of duplicative case-by-case requests.

"Initial requests" implies precedent, but reliance on prior determinations is not defined

NIH reviews initial requests to lower containment for RG3/RG4 work, while full IBC review applies when NIH previously approved such work at lower containment.

The proposal implies that subsequent requests may not require new NIH review, but it never defines "previously approved," substantial equivalence, acceptable deviations, or who determines that a prior decision applies.

3. Risk Assessment Framework and Utility of Risk Groups

Risk Groups remain a useful and important tool for hazard communication, institutional review, and initial characterization of biological risk. They provide a common language for communicating hazard characteristics across institutions and agencies. While Risk Groups do not fully account for experimental context, manipulations, or mitigation strategies and should not independently dictate

containment or oversight decisions, they remain an effective starting point when used with agent-specific and experiment-specific risk evaluation. Institutional risk assessment should remain the foundation for determining appropriate containment and other biosafety controls.

Mandatory Requirements and Advisory Technical Guidance Must Be Distinguished

The final Policy should also clearly distinguish mandatory NIH requirements from advisory technical recommendations in the BMBL. Although the BMBL appropriately serves as a primary technical resource for protocol-specific risk assessment, it does not independently establish federal jurisdiction, institutional review requirements, or enforceable compliance obligations. Institutions therefore need to know which practices are mandatory under the Policy, which are recommended starting points, when equivalent or alternative controls may be used based on a documented risk assessment, and what documentation is expected when professional biosafety judgment supports an approach that differs from a BMBL recommendation.

Without a clear distinction, institutions may treat advisory recommendations as mandatory requirements or, conversely, may apply institutional discretion where NIH intended a binding minimum. This ambiguity directly affects containment determinations, Assurance review, and what NIH will consider noncompliance.

Lack of Training Infrastructure

The policy heavily relies on investigator, BSO, and IBC risk assessments but provides little guidance regarding how competency will be achieved or maintained.

The policy requires training but does not establish:

- National training curricula;
- Core competencies;
- Risk assessment certification programs;
- Standardized case studies;
- Continuing education requirements; or
- Federal training resources.

Modernization should include a national framework for biosafety and biorisk management training to improve consistency across institutions. This competency infrastructure should complement, rather than replace, clear assignment of institutional and investigator training responsibilities.

“Genetic modification” is expansive enough to capture conventional selection and non-biological hazard programs

The definition includes stable alterations produced through passaging, reassortment, chemical means, or radiological means.

This creates several internal tensions:

- The policy is framed as biosafety oversight of biohazards, but the definition may capture organisms altered through chemical mutagenesis or irradiation.
- Genetically modified RG1 agents require delegated review, even if the modification does not plausibly increase risk.

- An organism selected through passage could be regulated as genetically modified even without recombinant or synthetic nucleic acid manipulation.
- The definition may turn attenuation by passage into "genetic modification," while the wild-type definition excludes organisms with deliberately introduced modifications.

Suggested correction: Distinguish deliberate genetic engineering from selection, adaptation, reassortment, induced mutagenesis, and incidental genomic change, then assign oversight based on the resulting risk rather than treating every category identically.

Mandatory BSL-2 for all GDMOs conflicts with risk-based environmental containment

All GDMOs must be conducted at a minimum of BSL-2, while the policy later recognizes geographically, environmentally, and genetically isolated settings as possible containment strategies.

This is difficult to reconcile for non-microbial organisms managed in specialized arthropod, aquatic, greenhouse, or ecological containment facilities that do not neatly map to BSL-2 laboratory design.

Influenza containment language is overbroad or grammatically ambiguous

The policy states that experiments with viruses containing genes or segments from specified strains must be conducted at BSL-3 enhanced containment. The wording does not establish whether this applies to:

- any segment;
- only segments associated with increased risk;
- a majority of the genome;
- infectious virus versus non-replicating constructs; or
- low-pathogenicity strains that share an H5 subtype but are not within the specified highly pathogenic lineage.

This is especially inconsistent with the preceding influenza rule, which uses the source of the **majority of segments** to determine containment.

4. Compliance, Enforcement, and Transparency

NIH should consider whether overly burdensome public-reporting requirements could discourage voluntary adoption of the framework by institutions not otherwise subject to the policy. Voluntary adoption is more likely when requirements are practical, scalable, and supported by clear guidance and shared resources. Encouraging voluntary compliance will require balancing transparency and accountability with implementation burden, confidentiality, and the need to preserve a strong reporting culture.

Public posting obligations conflict with privacy and de-identification principles.

Conflicting provisions: Institutions must post detailed IBC minutes and all incident reports publicly, subject to unspecified "appropriate and allowable" redactions. The policy separately requires NBDSAC data to be de-identified and protects voluntarily reported institutional and individual privacy.

Why it matters: The policy applies a clear de-identification standard to voluntary federal reporting but no corresponding standard to mandatory public posting. Without defined allowable redactions, institutions may either disclose too much or redact inconsistently.

Recused members may count toward quorum

The policy bars members from reviewing or approving projects in which they have a conflict, but permits them to count toward the voting quorum even when recused from the final determination.

Governance inconsistency: A quorum is ordinarily intended to ensure that a sufficient number of eligible members can deliberate and vote. Counting an ineligible member could permit approval by fewer non-conflicted members than the nominal quorum requirement suggests. The policy also does not specify the vote denominator after recusal.

Training is required but no minimum standard or responsible training authority is established

Separate from the national competency infrastructure discussed above, the policy does not clearly allocate responsibility for delivering, documenting, and verifying required training. The institution must ensure training for IBC members, BSOs, PIs, and laboratory staff, while the PI must provide or coordinate training for personnel. The policy also requires posting synopses of relevant staff training, but does not define required content, frequency, competency assessment, NIH-provided training, or documentation standards.

Result: Institutions and PIs have overlapping accountability, while neither has a defined compliance benchmark.

Assurance approval is a prerequisite, but the policy provides no transition mechanism

No covered research may be conducted until NIH approves the institution's written Biosafety Assurance. The policy applies to all existing awards and ongoing intramural studies six months after publication of the final policy. Assurances may be approved for up to four years.

Operational inconsistency: If NIH has not approved every recipient's assurance by the effective date, the literal text appears to halt ongoing covered research. The draft does not provide provisional assurances, deemed approval, phased implementation, or continued operation while an assurance is under review.

Record-retention periods are not mapped to record types

The policy cites a three-year federal award-record period but separately requires public posting of IBC minutes and incident reports for at least five years. It says some records may need longer retention and that records associated with awards must remain publicly available during the applicable period. It does not state the retention period for protocols, risk assessments, delegated reviews, training documentation, determinations, or assurance records.

Needed correction: A record-retention table identifying the triggering event, retention period, public-posting period, responsible custodian, and treatment of records covering multiple awards.

Incident-reporting categories overlap

Reportable categories include:

- any BSL-3/ABSL-3 or BSL-4/ABSL-4 incident;
- potential exposures involving injury or medical treatment;
- BSL-2/ABSL-2 exposures requiring agent-specific treatment;
- compliance violations at any level;
- lower-risk BSL-1/2 incidents that remain internally reportable; and
- minor spills that generally do not need reporting.

Ambiguities:

- "Any incident" at high containment is broader than the examples that follow it.
- "Basic first aid" and "agent-specific treatment" are not defined.
- A minor spill may be excluded, while another provision captures any BSL-1/2 incident.
- An animal bite or scratch must be reported to the IBC even without biohazard exposure, provided it occurred during research subject to the policy.
- A compliance violation may be reportable to NIH even if it presented no actual safety risk.

Incident Reporting Must Account for Preliminary and Evolving Information

Institutions may be required to classify an incident before medical, engineering, or investigative facts are complete. NIH should therefore define the minimum information required for the initial 24-hour notification and make clear that this notification is preliminary and need not include a completed root-cause analysis, final medical findings, or completed corrective actions. Institutions should be permitted to identify unresolved matters in the 30-day report, provide material updates as additional information becomes available, and reclassify an event in good faith as the facts develop.

NIH should also clarify how precautionary medical evaluation, diagnostic testing, observation, prophylaxis, and later medical findings affect the reporting determination. Medical consultation or prophylaxis may be provided out of an abundance of caution before the significance of an exposure is known and should not automatically determine the final incident classification.

When one event is reportable under multiple federal programs, NIH should permit a common factual investigation and core report, supplemented only by program-specific information. Federal systems should use a common event identifier or another reconciliation mechanism so that one underlying event is not treated as multiple incidents solely because it is reported to more than one program.

Public reporting may undermine the voluntary near-miss program

Lower-risk incidents must be reported internally, finalized, and publicly posted. Near-misses may also be voluntarily and confidentially submitted to NBDSAC, whose data must be de-identified.

Policy-design conflict: The federal system is designed around confidentiality and de-identification, while the institutional system requires public reports. The boundary between a mandatory "lower-risk incident" and a voluntary "near-miss, secondary failure, or procedural issue" is not defined.

The policy refers to NIH's "final response" without a response deadline

Institutions must post reportable incident information within 30 days of NIH's final response, and NIH must review and respond "in a timely manner." No defined deadline or endpoint establishes when NIH's response is final.

Result: Institutions cannot control or predict the public-posting date, and an open-ended NIH review could leave a report in provisional status indefinitely.

5. Implementation Resources and Guidance Needs

Major Comments

Six-Month Implementation Timeline Is Unrealistic

The policy becomes effective six months after publication of the final version and appears to require approved Biosafety Assurances before research may continue.

Even institutions with mature biosafety programs will likely need to:

- Revise policies and procedures;
- Develop assurance processes;
- Build new public web infrastructure;
- Create redaction procedures;
- Modify protocol management systems;
- Develop new training materials;
- Expand protocol inventories;
- Train investigators, IBC members, and biosafety staff; and
- Establish new incident reporting workflows.

For smaller universities, hospitals, teaching institutions, and emerging research organizations, these changes may require substantial new staffing and infrastructure investments. Although NIH has issued draft templates for incident reporting and IBC meeting minutes, institutions do not yet have the full set of training resources, databases, guidance documents, risk assessment tools, assurance materials, and implementation resources needed to support this transition.

NIH should provide a minimum 24-month phased implementation period following publication of the final Policy and the foundational implementation materials necessary for compliance. Implementation milestones should be tied to the availability of final definitions, decision tools, templates, Assurance instructions, reporting systems, training materials, redaction standards, and NIH review capacity, rather than running solely from publication of the final Policy. If those materials are delayed, NIH should use defined conversion periods, grandfathering, provisional or deemed Assurance mechanisms, and other transition measures so that institutions do not lose usable implementation time or have to suspend otherwise compliant research.

NIH Should Establish Federal Review Service Standards

The draft assigns institutions numerous fixed deadlines and makes some research activities dependent on prior NIH action, but it does not establish corresponding operational expectations for federal review. NIH should publish service standards for Biosafety Assurance review, containment determinations, incident follow-up requiring federal direction, and other decisions that may delay institutional action.

These standards should address submission completeness, expected review timeframes, requests for additional information, pause-and-restart rules, written decisions, escalation pathways for delayed reviews, and the status of research when a complete and timely submission remains pending through

no fault of the institution. NIH should also establish continuity procedures for a lapse in federal appropriations, government closure, system outage, or other period during which NIH is unable to act.

Institutions should not be required to suspend otherwise compliant research or incur a compliance finding solely because a federal administrative review remains incomplete or NIH systems are unavailable.

NIH Should Establish a National Biosafety Determination and Risk Classification Database

The draft policy creates multiple mechanisms through which NIH may make determinations regarding containment levels, risk classifications, and lower-containment approvals. However, the policy does not describe how these determinations will be communicated to the broader research community or whether previously issued determinations may be relied upon by other institutions.

Without a centralized system, institutions may be required to repeatedly submit similar requests regarding the same organisms, experimental systems, or containment questions, resulting in duplicative effort both for institutions and NIH. This concern is particularly relevant for novel, emerging, zoonotic, or poorly characterized biological agents, where local institutions may lack access to prior federal determinations.

NIH should establish and maintain a publicly searchable database similar to Health Canada's ePathogen system that includes:

- Risk Group classifications;
- NIH containment determinations;
- Approved lower-containment decisions;
- Agent summaries;
- Relevant precedent decisions; and
- Associated guidance documents.

Such a resource would improve consistency, reduce duplication, increase transparency, and support risk-based decision making across the research enterprise.

Standardized Templates and Implementation Resources Require Further Development Prior to Implementation

The draft policy appropriately recognizes the importance of implementation support and NIH has already taken an encouraging first step by publishing draft templates for both incident reporting and IBC meeting minutes. Standardized forms have the potential to improve consistency across institutions and promote transparency regarding biosafety oversight activities.

NIH should clarify whether its templates are mandatory, recommended, or illustrative. Compliance should be based primarily on required content and performance standards rather than use of a particular document format. Many institutions already use electronic compliance-management systems that generate agendas, attendance records, voting outcomes, protocol summaries, approvals, and meeting records from structured data. Institutions should be permitted to continue using those systems and alternative formats when all required information is captured, retained, and made publicly available as required.

A minimum-content approach would promote consistency while avoiding unnecessary system modifications or manual duplication of information already maintained in institutional records. NIH should distinguish clearly between required data elements and model templates intended to assist institutions.

The current draft templates raise significant implementation concerns that should be resolved prior to policy implementation. The draft IBC meeting minutes template requires substantial documentation of protocol summaries, risk assessments, training, occupational health considerations, biosafety level determinations, committee discussions, delegated review activities, incidents, inspections, and other committee business. Similarly, the incident reporting template requires extensive documentation regarding personnel, training history, SOP compliance, occupational health considerations, corrective actions, and root cause analysis.

While transparency is an important objective, the level of detail contemplated by these templates may create substantial administrative burden for institutions and IBCs. In particular:

- The meeting-minutes template appears to require documentation of a significant portion of the committee's deliberative process and risk assessment rationale.
- The meeting-minutes template requires documentation of delegated-review approvals within publicly posted minutes, potentially reducing some of the efficiency benefits of delegated review.
- Both templates require public disclosure of information that may traditionally have been retained within institutional records rather than prepared for public consumption.
- The incident-reporting template expressly states that PI names, biological agents, grant numbers, and other information commonly available from public sources may not be redacted. While intended to increase transparency, this approach may have unintended consequences for reporting culture, personnel safety, and research security. Publicly associating named investigators and identifiable research personnel with specific biological agents, animal studies, facilities, or incidents could facilitate harassment, intimidation, targeted activism, or other threats, particularly in connection with controversial or sensitive research. The potential risks extend beyond PIs to animal care personnel, veterinarians, biosafety professionals, laboratory staff, and other employees associated with the work. The draft provides de-identification and privacy protections for information submitted to the National Biosafety Data and Safety Analysis Center but does not establish a comparable risk-based framework for publicly posted institutional incident reports. NIH should establish clear standards permitting information to be redacted when disclosure could reasonably create personnel-safety, research-security, privacy, or harassment concerns without materially advancing transparency or public-health objectives.
- The draft policy and templates do not clearly define the boundaries of allowable redaction practices, leaving institutions vulnerable to inconsistent implementation and potential disputes regarding appropriate public disclosure.

In addition, several key implementation resources are still absent. Institutions will need additional guidance and standardized tools to ensure consistent implementation, including:

- Biosafety Assurance templates;
- Comprehensive risk assessment templates and examples;
- Example completed incident reports and meeting minutes;
- Training materials for IBC members, BSOs, Investigators, and Institutional Officials;

- Guidance documents describing acceptable implementation approaches for institutions of varying size and complexity;
- Clear redaction guidance for public meeting minutes and incident reports;
- National databases for containment determinations and Risk Group classifications;
- Guidance regarding what qualifies for delegated review versus full committee review; and
- Interagency guidance clarifying relationships among NIH, USDA, CDC, FDA, EPA, OSHA, and Select Agent requirements

NIH should pilot test the proposed templates with institutions representing a range of biosafety program sizes and maturity levels before finalizing these requirements. Feedback from such pilots would help ensure that transparency objectives are achieved without creating unnecessary administrative burden or inadvertently discouraging incident reporting. Further refinement of these templates and supporting implementation resources would likely improve both consistency and long-term compliance outcomes. Institutions should be afforded an opportunity to review draft implementation materials before final policy implementation because several critical operational details appear to depend on future guidance rather than the policy text itself.

Material Revisions and Implementation Requirements Should Receive Stakeholder Review

Because several critical requirements remain undefined and may be resolved through later guidance, templates, or substantial revisions to the Policy, NIH should provide stakeholders an opportunity to review and comment on materially revised policy language and major implementation materials before they become binding. At a minimum, institutions should be able to evaluate the complete package of scope definitions, review criteria, Assurance requirements, reporting standards, public-disclosure rules, and transition procedures before implementation obligations are finalized.

Modernization Should Not Become an Unfunded Mandate

The draft policy substantially expands biosafety oversight responsibilities, increases transparency requirements, establishes new reporting obligations, and requires expanded institutional infrastructure. However, the policy does not identify corresponding funding mechanisms to support these activities.

Implementation of the proposed requirements will likely require:

- Additional biosafety personnel;
- Expanded administrative support;
- Information technology infrastructure;
- Public reporting systems;
- Training development;
- Increased protocol management capacity; and
- Enhanced institutional oversight activities.

For many institutions, particularly smaller institutions, teaching-focused universities, hospitals, and emerging research organizations, these activities may represent substantial new costs.

NIH should consider mechanisms to support implementation, including:

- Dedicated biosafety supplements;

- Allowable Facilities and Administrative (F&A) recovery for biosafety activities;
- Workforce development initiatives;
- National training programs; and
- Shared implementation resources.

Expanding oversight without corresponding support may create significant implementation challenges and increase disparities between large and small institutions.

Conclusion

The draft successfully expands biosafety oversight to address modern biological risks, but it does not achieve one of the modernization initiative's most important objectives: elevating biosafety oversight to an institutional position comparable to human-subject and animal-care oversight. IBCs and BSOs are assigned substantially greater responsibilities without proportional authority, independence, institutional standing, leadership access, staffing, or resources. The draft also leaves significant gaps and ambiguities concerning plant and environmental risks, interagency coordination, low-risk research, incident reporting, public disclosure, and implementation. Absent enforceable institutional expectations and adequate implementation support, the policy risks creating greater accountability without providing the infrastructure necessary to meet it. Modernization should not merely enlarge the biosafety compliance function. It should establish IBCs and qualified biosafety professionals as empowered, appropriately supported, and institutionally recognized pillars of research oversight within a coordinated, risk-based, and sustainable federal framework.

Sincerely,

Megan Shoff, PhD, RBP, CSP

165. University of Maryland, College Park (UMD), & University of Maryland, Baltimore (UMB)

I am responding: On behalf of an organization

Name:

Name of Organization: University of Maryland, College Park (UMD), & University of Maryland, Baltimore (UMB)

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Biosafety-Policy_UMB_UMD_Comments.pdf

UNIVERSITY OF MARYLAND

UNIVERSITY of MARYLAND BALTIMORE

OFFICE OF THE VICE PRESIDENT AND CHIEF RESEARCH OFFICER

October 14, 2026

Office of Science Policy
National Institutes of Health
8701 Rockledge Drive, Suite 750
Bethesda, MD 20892

SUBJECT: Joint Transmittal of UMB and UMD Institutional Biosafety Committee Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Dear Members of the NIH Office of Science Policy:

On behalf of the joint research enterprise at the University of Maryland, Baltimore (UMB) and the University of Maryland, College Park (UMD), I submit our institutional responses to the **Draft NIH Biosafety Policy for Research Involving Biohazards.** Transmitted with this letter are reports authored independently by the Institutional Biosafety Committee (IBC) leadership and Environmental Health and Safety biosafety teams from both campuses. As summarized below and expanded in the attached submissions, our two institutions have serious concerns about the proposed regulatory framework's operational and administrative feasibility.

- **Unnecessary Administrative Burden vs. Risk Calibration:** We have deep concern that replacing the NIH Guidelines with mandatory, standardized oversight across all biohazards would create an unsustainable burden for PIs, biosafety officers, and committee members without delivering a proportionate improvement in safety.
- **Disproportionate Oversight of Low-Risk Research:** We strongly urge the NIH to retain exemptions for low-risk research activities. Eliminating these exemptions would inundate the oversight committees with hundreds of low-hazard filings, diverting critical resources away from higher-consequence biohazards.
- **Inflexible Three-Year De Novo Reviews:** Mandating that protocols be closed and resubmitted *de novo* every three years introduces unnecessary disruption for investigators.
- **Protection of Investigator Privacy & Incident Transparency:** Accelerated public disclosure of meeting minutes and mandatory inclusion of personal investigator details in incident reports create significant personal security and harassment risks for researchers. Furthermore, publicizing detailed incident reports risks establishing a punitive climate that would disincentivize transparent, voluntary reporting.
- **Governance Flexibility & Timeline Extension:** As leading research universities, UMB and UMD need institutional authority and autonomy to adapt their oversight procedures to local context. Both campuses emphasize that the proposed six-month implementation window is impractical and respectfully request an extension to at least one year to allow adequate time for PI training and systems reconfiguration.

Our institutions are happy to work collaboratively with the NIH to establish a balanced, risk-calibrated biosafety policy that protects researchers and the public while maintaining scientific progress.

Sincerely,

[redacted]

Vice President and Chief Research Officer

Section / item	Comment	Suggested change
Entire Document	The draft Policy leaves several aspects of institutional biosafety governance and implementation incompletely defined.	Clarify the minimum requirements while allowing institutions appropriate authority and flexibility to establish policies, assign responsibilities, and address matters not explicitly covered by the Policy based on their institutional needs and risk assessments.
Entire Document - Omission	The draft policy does not address the use of AI in developing biological agents.	Add guidelines for the use of AI in developing biological agents (viruses, recombinant molecules). Language on how to approach biological agents generated by AI should be added.
Other Comments	The Policy relies heavily on headings and bullet points, making specific provisions difficult to cite and cross-reference consistently	Adopt a consistent hierarchical numbering system and assign each substantive requirement a stable, unique citation identifier (e.g., III.B.2.a.(1))
Section II - General definitions	The definition of toxins is limited to proteins and peptides, excluding other types of biologically derived toxins, such as glycosides, alkaloids, and lipopolysaccharides.	Clarify whether the definition is intentionally limited to protein and peptide toxins for the purposes of this policy, or should be expanded to include other types of toxins.
Section II - Scope	The draft defines biohazards primarily in terms of risks to human health, which may exclude biological agents that pose significant risks to animal health, plant health, agriculture, or the environment. This may create gaps compared with the current NIH Guidelines.	Clarify whether animal, plant, agricultural, and environmental biohazards are within the scope of the Policy. If they are intentionally excluded, clearly state this and explain how the existing plant and environmental biosafety provisions of the NIH Guidelines will be addressed under the new framework.
Section II - Scope	The inclusion of “clinical settings” within laboratory research creates uncertainty as to whether routine collection of human biospecimens for research, such as venipuncture, requires IBC oversight even when no biohazard is manipulated or administered.	Clarify that routine clinical specimen collection alone does not require IBC review solely because specimens are collected for research. Subsequent handling or manipulation of the specimens should be evaluated separately based on the associated biosafety risk.
Section II - Scope	The definition of “biomedical research in laboratory settings” does not clearly address biosafety-relevant field research or non-research biological activities, such as teaching laboratories in academic institutions. This may create both gaps in oversight and unnecessary expansion of IBC	Clarify whether biosafety-relevant field research and non-research biological activities, such as teaching laboratories, are within the scope of the Policy. Clearly define the applicable scope and criteria so institutions can consistently determine which activities are subject to Policy requirements.
Section II - Scope	The proposed six-month implementation period may be insufficient given the substantial changes in institutional responsibilities, oversight processes, training, procedures, and compliance systems required by the new Policy.	Provide at least 12 months between publication of the final Policy and its effective date to allow institutions sufficient time for effective implementation.
Section II - Scope	The draft policy does not clearly address oversight of plant genetic modification research.	Clarify whether and how plant genetic modification research is covered under the policy.
Section III-A - Responsibilities of the Institution	The Policy does not clearly define its expectations for an Occupational Health and Safety Program (OHSP) or how it should relate to an institution’s existing occupational health and safety program.	Clarify whether an existing institutional Occupational Health and Safety Program that covers the applicable hazards satisfies the Policy, or whether a separate Policy-specific program or plan is required. If additional requirements apply to research subject to the Policy, clearly define the minimum expectations for the OHSP.
Section III-A - Responsibilities of the Institution	The Policy references an “IBC Contact” but does not define the role or its responsibilities in supporting IBC administration and compliance.	Clarify the role and responsibilities of the IBC Contact and whether institutions have flexibility to assign these administrative functions based on their organizational structure.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The statement that minor spills of low-risk agents “generally do not need to be reported” does not specify whether this refers to reporting to NIH, the IBC, or both.	Clarify the applicable reporting level and distinguish between institutional/IBC reporting and external reporting to NIH.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The expectation to include or have access to an individual knowledgeable in “community attitudes” appears to overlap with the required unaffiliated IBC members, who are specifically appointed to represent the interests of the surrounding community.	Clarify whether the required unaffiliated community members satisfy the “community attitudes” expectation, or whether NIH intends this to represent a separate area of expertise requiring an additional member or ad hoc consultant.

Section / item	Comment	Suggested change
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft defines the BSO primarily through operational and technical duties and does not adequately describe the BSO's broader role, authority, or oversight responsibilities within institutional biosafety governance. It is also unclear whether the listed BSO duties must be performed personally by the designated BSO or may be delegated to qualified biosafety personnel.	Define the BSO as the institution's designated biosafety professional responsible for leading or administering the biosafety program and providing technical oversight. Clearly establish the BSO's authority to identify, assess, communicate, and escalate biosafety concerns. Clarify that appropriate duties may be delegated to qualified biosafety personnel, such as Assistant or Associate BSOs or Biosafety Specialists.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The proposed review pathways may not consistently reflect relative risk. Primary cells that may contain adventitious agents require full IBC review, while research involving known RG2 wild-type biological agents is eligible for delegated review.	Require full IBC review for deliberate propagation or manipulation of known RG2 wild-type biological agents. Allow primary cells with potential adventitious agents to undergo delegated review when appropriate, with escalation to full IBC review based on the specific hazards and experimental procedures.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required.	Approval should be granted for a period not to exceed four years, at which time a de novo registration submission and review is required.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Petitioning NIH for determination of the minimum biocontainment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available in the BMBL.	Petitioning NIH for determination of the minimum biocontainment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available in the most current version of the BMBL.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Petitioning NIH for determination of the minimum biocontainment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available in the BMBL.	Envirnomental isolates can be kept in secure cryogenic storage but not actively utilized until authorized.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Any incidents involving exposures at BSL-2/ABSL-2 that require agent-specific treatment beyond basic first aid; and	Completely remove this section for BSL-2 as the BSL-2 risk assessment and definition mean that there is no risk to the community.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The requirement for de novo registration and review every three years creates an unnecessary administrative burden for ongoing research projects.	Allow periodic renewal of existing IBC registrations without requiring de novo registration and review.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft policy does not clearly define the authority of the IBC and BSO to suspend research in cases of noncompliance.	Clarify the authority of the IBC and BSO to suspend research when violations of the NIH Biosafety Policy occur.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	"No member of the IBC may be involved in the review or approval of a project in which they are or expect to be engaged, or in which they have a direct financial or any other conflict of interest, except to provide information requested by the IBC to facilitate their review. Such members can be counted for purposes of establishing a voting quorum for the meeting even if they recuse themselves from the final determination related to the project."	Provide further definition of engagement -> What is the threshold for engagement? For example, if an IBC member works in or is affliated with a core facility that a researcher will (or might) eventually use for the project, is the IBC member considered "engaged"?
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	"Approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required." - For a large institution that might have a 4 year review process reducing the approval time will incur a larger review burden on IBC committees.	If this is a reduction in the timeframe from existing, maybe for lower risk work that is unlikely to change, keep current rules to avoid overburdening IBC committees, particularly at large institutions
Section III-C - Responsibilities of the Principal Investigator (PI)	Research with primary cells that may be contaminated by adventitious agents.	Research with primary cells or tissues that may be contaminated by adventitious agents.
Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	Sections IV-2 and IV-3 appear to overlap for genetically modified research, creating uncertainty as to when full IBC review versus delegated review is required.	Clarify the relationship and precedence between Sections IV-2 and IV-3 and provide clear criteria for determining when genetically modified cells, viruses, or organisms qualify for delegated review rather than full IBC review.
Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	Section IV-3 requires prior delegated review and approval for a broad range of lower-risk activities. For well-defined minimal-risk research, mandatory prior approval may create administrative burden disproportionate to the biosafety risk.	Allow defined minimal-risk activities within Section IV-3 to proceed through notification or registration without prior approval. Institutions should retain flexibility to screen these activities and elevate them to delegated or full IBC review when additional risk factors are identified.
Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	The delegated review of low-risk work (BSL-1) does not seem necessary and an exemption for such review should be maintained	Maintain exemptions from IBC review for qualifying low-risk (BSL-1) research activities.

Section / item	Comment	Suggested change
Section V - Risk Assessment and Mitigation for Research Involving Biohazards	The draft policy does not provide a standardized risk assessment template to support consistent implementation across institutions.	Provide a recommended risk assessment template to promote consistency while allowing institutional flexibility.
Section V-D - Requirements and Considerations for Risk Assessment of Manipulations of Biohazards	The Policy identifies “large culture volumes” as a factor that may increase risk but does not define what constitutes a large volume or when additional large-scale risk assessment is expected.	Define a threshold or clear criteria for identifying large-volume culture research. Exceeding the threshold should trigger additional risk assessment, rather than automatically requiring a higher BSL, with containment determined based on volume together with the agent, concentration, aerosol potential, system design, and other relevant risk factors.
Section V-E - Risk Mitigation Strategies and Laboratory Containment	The draft requires BSL-3 enhanced containment and an occupational health plan for specified influenza research but does not define the minimum requirements for either or clarify whether a separate influenza-specific occupational health plan is required.	Define the minimum requirements for BSL-3 enhanced containment and the occupational health plan required for the specified influenza research, or directly reference applicable implementation guidance that defines these requirements
Part 1. Institutional Information	The draft allows the PI’s name to be included in incident reports while excluding other personally identifiable information. Identifying the PI may unnecessarily associate an individual with an incident and detract from a learning-focused, non-punitive reporting process.	Do not include the names of the PI or other individuals involved in incident reports. Incident reports should focus on the incident itself, including what occurred, contributing factors, and corrective actions, rather than identifying individuals.
Other Comments	The meeting minutes template does not clearly distinguish among full IBC review, delegated review, and periodic/renewal review. If a notification/registration-only category is adopted, this should also be reflected in the template	Add separate or clearly identified categories for full IBC review, delegated review, and notification/registration-only activities, with documentation proportional to the level of oversight. Clarify that periodic/three-year reviews may use the same format as new registrations if they are conducted as de novo reviews.
	The IBC Minutes Template unnecessarily involved and could be shortened without losing relevant information and transparency.	Simplify the IBC Minutes Template to reduce administrative burden
	The requirement to publicly post full IBC meeting minutes creates unnecessary administrative burden related to redactions and raises potential privacy and security concerns.	Allow a standardized meeting summary with essential information, such as attendance, protocol reviews and approvals, and key policy discussions, to be publicly posted instead of full meeting minutes.

Section / item	Comment	Suggested change
Section II - Scope	Toxins included in scope of the policy. 1) Toxins are of biological origin, but by their function, they are better classified as chemical agents and have Safety Data Sheets outlining precautions. The IBC would need chemical safety (different) expertise to do an appropriate risk assessment beyond the SDS. One example: Toxins are defined as "a protein or peptide produced by living organisms that causes harm in humans." That broad definition would include snake venom, which would be beyond the expertise of microbiologists. 2) As toxins are a frequent reagent, we expect somewhere around 30-200 PIs to now have to submit for this work, many of whom may not have had to write a protocol before.	Remove toxins from scope, they are better classified as chemical reagents.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	"Approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required." 1) Closing a protocol and reopening a new one creates logistical challenges in the online CICERO system, especially for IRB-connected IBC protocols. This relationship includes built-in features, including approval blocks, which would be difficult when the parent IRB protocol is not closing and reopening. 2) Many PIs are going to copy and paste, so while the intentions of forcing a protocol to close and reopen might be good, it is a large administrative burden with no real payoff.	1) Eliminate the three year closure and de novo submission requirement, 2) Allow a protocol to remain open, but require it to be re-reviewed (by FCR if appropriate) every three years, or 3) Exempt IRB-connected studies from the three-year closure requirement.
Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	"The BSO's duties include conducting periodic inspections to ensure that laboratory biocontainment facilities and equipment are functioning properly, biosafety standards are rigorously followed, and IBC approval conditions for the conduct of research are being followed." 1) It is unclear how often these inspections must occur (e.g., once in the three year life cycle or annual). 2) With the expanded scope, these inspections may involve low risk protocols, including purchasing trangenic rodents, where general lab safety or IACUC inspections are already sufficient. 3) For IRB-related IBC protocols, the location is often multiple clinics and/or hospitals. It is unclear what the expectation would be for inspecting off-campus clinical areas. The IBC has reviewed protocols in Mali and Nigeria, which would be logistically challenging to inspect. Note: this concern would also be relevent for additional types of off-campus field work. 4) The UMB Office of Animal Welfare Assurance has three FTE dedicated to Post Approval Monitoring (PAM) inspections. PAM inspections would be added to biosafety staff in additional to their other responsibilities. There is concern about the level of staffing needed, especially considering other increases in workload related to this policy. 5) It is unclear if a safety inspection can adequately verify equipment functionality.	Make inspections recommended and based on a risk assessment.

Section / item	Comment	Suggested change
Section IV-1 - Research That Requires NIH and IBC Approval Before Initiation	"Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL." It is unclear if work with agents like pangolin coronavirus (not new, used at BSL-3 for years) needs to stop and wait for clearance.	
Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	Requires Full Committee Review (FCR): "Research involving genetically modified cells" The purchase and use of pre-made genetically modified cells is low risk or the risk is limited to the potential presence of bloodborne pathogens.This would be more reasonable at the Delegated Member Review level.	As with the previous NIH Guidelines, base the review path on a risk assessment of potential creation methods (e.g., viral vectors) or on the planned use (e.g., engrafted into animals).
Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	Requires Full Committee Review (FCR): "Research involving toxins listed as select agents" 1) As mentioned above, toxins align more closely with chemical hazards than biohazards. There are Safety Data Sheets available, so full committee review is overkill. 2) For those institutions that are registered for select agents, this process may be redundant to the required Due Diligence program.	1) Remove toxins from scope of policy or 2) Allow Delegated Member Review.
Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	Requires Full Committee Review (FCR): "Research with primary cells that may be contaminated by adventicious agents." Precautions are outlined by the OSHA Bloodborne Pathogens Standard. Requiring FCR for this is disproportionate for the level of risk and expertise needed. It is worth noting that work with a known culture of Hepatitis B virus is permitted to be DMR while a cell that might contain HBV is FCR.	Allow Delegated Member Review.
Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	Requires Full Committee Review (FCR): "Research with primary cells that may be contaminated by adventicious agents." It is unclear if this includes any human study that involves a blood draw (as blood could meet the definition of a primary cell that may be contaminated by BBP). This could add approximately 50-80 protocols to FCR every month. It would lead to significant, unnecessary delays in time to activation.	Please clarify if a blood draw is included in this definition.
Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	Requires Full Committee Review (FCR): Clinical research involving Risk Group 2 or higher biological agents. 1) While the level of risk is admittedly higher here, it is worth noting that this work is already going through the IRB for patient safety. 2) This will add to time to activation, which has been a concern for the IRB.	N/A

Section / item	Comment	Suggested change
Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	Requires Delegated Member Review (FCR): "Research with transgenic organisms at BSL-1/ABSL-1." There is no exemption for transgenic rodents. 1) The only risk for use of a transgenic animal would be the biosecurity concerns around escape, which are under the purview of the IACUC. This is a redundant effort. 2) We estimate approximately 250 studies that involve transgenic rodents. This is significantly increased administrative burden when the risk is negligible.	As with the previous NIH Guidelines, make an exemption for the use, breeding, and purchase of transgenic rodents where risk is negligible.
Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	Requires Delegated Member Review (FCR): "Research with plasmids" There is no longer an exemption for everyday cloning in nonpathogenic *E. coli.* Note that UMB has expected IBC submission for cloning, but as an exempt procedure, it was not NIH reportable when we found that a PI had not submitted.	As with the previous NIH Guidelines, make the use of plasmids in non-pathogenic *E. coli* exempt.
Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	Requires Delegated Member Review (FCR): "minor amendments to previously approved submissions." What is considered a minor amendment is not defined. Does it include a new gene expressed by a previously approved vector (where the risk assessment in place is sufficient)? Or is it meant to be administrative details like personnel amendments only?	Define "minor amendments."
Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	Requires Delegated Member Review (FCR): "Research with well-characterized cell lines." What is considered well characterized? Is it pathogen tested? It is possible to not be a primary cell (listed for FCR) or a well characterized cell line (listed for DMR), so these materials would presumably default to FCR.	Define "well characterized."
Other Comments	There seems to be a fundamental misunderstanding of where administrative burden comes from related to IBC protocols. Some experiments have moved from FCR to DMR, which will help with time to activation and committee members' time. However, they have eliminated exemptions for low risk materials (now all DMR) and expanded the scope, so there is a massive increase in what will need to be submitted to the IBC. The writing of a protocol and its preliminary review are the most time consuming aspects for PIs and the biosafety team respectively.	As with the previous NIH Guidelines, bring back exemptions for predefined categories that are extremely common and low risk.

Section / item	Comment	Suggested change
Other Comments	The comparison table released by the NIH OSP has a row on clinical protocols that only lists the "Products that are capable of shedding, replicating, or integrating; Products that require higher risk manipulations (e.g., aerosolization, bladder infusions); and RG2 or higher wild type biological agents (e.g., challenge experiments for medical countermeasures)" as needing FCR. It is unclear if use of a select toxin (e.g., botox) in a clinical setting requires FCR as select toxins are explicitly listed above that on the draft policy list. (Note: This is connected to the blood draw concern mentioned above for which it is unclear what their expectations for clinical protocols are due to the poor organization of the list.)	Make clear what clinical protocols require FCR, only the three bullet points under the clinical sentence or anything in the FCR category.
Other Comments	Because the draft policy greatly expands the scope of what is covered, more incidents will need to be reported. This includes reports of unapproved research for experiments that were previously exempted due to low risk.	Make incident reporting risk based.
Part 3. Incident Narrative	By including PI name, a person's position, and potentially using a specifc pronoun, it would become possible to figure out the identity of an injured person or a person involved in an accident (e.g., spill). This could be referenced by anyone on the internet, including prospective employers. We anticipate some accidents to go unreported due to fear of details being posted on the website.	Not require personnel details if posted on a website. Could post a general incident report summary annually.
Overall format, length & usability	When timed, we found it takes an analyst about 30-40 minutes longer per protocol to write minutes in this level of detail. Considering the increase in total scope of the policy, creating minutes is near a complete FTE. Many additional details, such as specifics of the material used, will likely be	As with the previous NIH Guidelines, list what information must be included and allow institutions to meet the requirements as they determine appropriate.
New IBC Registrations and Amendments for Review	The section entitled "Readout of any projects approved by delegated member review" is in the middle of details needed for each protocol. This is confusing and it is difficult to determine if DMR protocols can be just listed or need more details.	Clarify differences between minutes requirements for DMR versus FCR.

166. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biological Safety Professional

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Define the policy's organizing terms-- Add a clear definition of "biohazard" and use it consistently throughout the policy. Define "biological agent" neutrally, then distinguish biological agents that meet risk-based criteria for oversight. Align the definitions of biomedical research, laboratory research, genetic modification, genetically modified organism, transgenic organism, toxin, prion, self-aggregating protein, well-characterized cell line, and clinical research involving biohazards.

Establish an exposure-based scope test-- State that a material or activity is covered when there is a credible pathway of exposure or release and a plausible risk to human health, public health, animal or plant health, or the environment, as applicable. Distinguish plausible risk from remote theoretical risk.

Publish an applicability matrix-- Identify activities requiring no review, administrative review, delegated review, full IBC review, and NIH plus IBC review. Include examples involving blood and other potentially infectious materials, environmental samples, validated inactivated materials, routine cell lines, transgenic rodents, plant-associated microorganisms, diagnostic work, core facilities, clinical sites, affiliates, leased space, and off-site collaborations.

Clarify plant, animal, agricultural, and environmental coverage-- State expressly whether animal-only pathogens, plant pathogens, genetically modified plants, and environmental-release research are within scope. Explain when another federal agency's oversight replaces, partially satisfies, or operates concurrently with NIH-policy and IBC requirements.

Narrow the definition of genetic modification-- Limit mandatory oversight based solely on genetic modification to intentional engineering or other changes that may affect biological risk. Distinguish deliberate engineering from conventional selection, adaptation, passaging, reassortment, chemical mutagenesis, radiological mutagenesis, and incidental or collateral changes. Base the review pathway on the resulting phenotype, intended function, and risk.

Calibrate toxin oversight to meaningful risk-- Define oversight using factors such as potency, quantity, concentration, biological activity, formulation, and route of exposure. Establish De Minimis thresholds or exemptions where appropriate. Clarify the status of inactive derivatives, isolated subunits, peptides, low-risk toxin preparations, and nucleic acids encoding toxins.

Limit the self-aggregating protein category-- Clarify that heightened oversight applies to transmissible, experimentally propagating, or disease-associated self-aggregating proteins, rather than ordinary protein aggregation without comparable biological risk.

Create a distinct clinical-research framework-- Define clinical research involving biohazards separately from laboratory research and provide clinical-specific review and
mitigation criteria. Clarify manufactured cell products, direct vector administration, shedding, replication or integration, higher-risk administration procedures, multicenter responsibilities, expanded-access exclusions, and risk-based endpoints for IBC oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Establish a clear precedence rule-- State which review category controls when Sections IV-1, IV-2, and IV-3 overlap. Provide a decision table with examples for NIH review, full IBC review, delegated review, administrative registration, documentation only, and exclusion.

Reserve federal preapproval for defined high-risk or uncertain research-- Limit mandatory NIH preapproval to circumstances involving substantial uncertainty, genuinely novel hazards, or potentially significant public-health or environmental consequences. Permit IBCs to make local determinations for well-characterized agents when adequate information supports the assessment.

Make NIH determinations reusable-- Create a searchable national repository of NIH risk-classification and containment determinations. Define substantial equivalence, permissible deviations, required documentation, who decides whether precedent applies, and which changes require a new petition.

Create lower-burden pathways for minimal-risk work-- Allow documented institutional screening, exemption, or registration for established well-characterized cell lines, commercial transgenic animals maintained at ABSL-1, genetically modified RG1 organisms, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, and low-risk toxin work. Preserve institutional authority to elevate review based on local risk factors.

Define delegated-review procedures-- Specify reviewer eligibility, conflict-of-interest requirements, access to review materials, criteria for elevation, treatment of initial submissions and amendments, and the status of approvals. Define “minor amendment” as a change that does not materially alter the risk assessment, containment, or principal mitigation strategy.

Make reporting of delegated approvals proportionate-- Allow a concise approval report to the IBC, with complete records retained for oversight and review. Clarify whether post-approval reporting is informational and under what circumstances a delegated decision may be reconsidered.

Adopt risk-based renewal and post-approval review-- Replace a uniform renewal interval with an approach that permits more frequent review of higher-risk or changing research and longer intervals for stable lower-risk activities. Distinguish de novo renewal, continuing review, minor amendments, and administrative changes.

3. Continued utility of Risk Groups: Retain RGs as a starting point, not a final determination-- Use Risk Groups for initial hazard characterization and communication, while requiring experiment-specific and site-specific assessment before assigning containment or oversight. State expressly that RG and BSL or ABSL classifications are related but not interchangeable.

Require phenotype- and procedure-based assessment of modified agents-- Begin with the parent agent, then evaluate how modifications affect pathogenicity, virulence, transmissibility, host or tissue range, replication competence, environmental persistence, toxicity, allergenicity, countermeasures, and exposure routes. Include procedure, scale, aerosol generation, sharps, animal work, personnel expertise, facility capability, and available mitigations.

Clarify the hierarchy of policy and guidance-- Explain how binding policy requirements, BMBL recommendations, RG classifications, NIH determinations, and institutional risk assessments interact and how conflicts are resolved.

Expand worked examples and national reference resources-- Provide examples for attenuation, replication-defective constructs, opportunistic agents, unclassified agents, validated inactivation, toxins, prions, gene-drive systems and components, synthetic or AI-designed sequences, multi-source constructs, and influenza reassortants, pseudotypes, strains, and segments. Maintain a current, publicly accessible RG and containment resource.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Separate core safety principles from award-administration requirements-- Identify which provisions represent broadly applicable biosafety practices and which are specific to NIH assurances, public posting, recordkeeping, federal notification, or grant administration.

Provide shared resources and participation incentives-- Offer model policies, training, risk-assessment tools, access to national containment determinations, and participation in confidential de-identified incident-learning systems. Permit shared, consortium, external-IBC, and mutual-aid models for organizations with limited internal capacity.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reporting Create a risk-based reporting decision table-- Define incident, confirmed exposure, potential exposure, laboratory-acquired infection, loss of containment, release, minor spill, near miss, basic first aid, agent-specific treatment, compliance violation, and equipment or facility failure. Distinguish immediate NIH notification, later full reporting, local IBC review, institutional management, and voluntary confidential reporting.

Focus federal reporting on biosafety-significant events-- Require federal reporting for credible exposures or releases, potential laboratory-acquired infections, materially compromised containment, significant unauthorized work, and other events with meaningful public-health or community implications. Exclude

routine occupational injuries unrelated to biohazard exposure or release.

Clarify ambiguous reporting scenarios-- Address precautionary medical evaluation, post-exposure prophylaxis, adventitious agents, mixed or uncertain exposures, first-aid-only events, animal incidents, properly contained and disinfected spills, administrative deficiencies, and equipment failures when redundant containment remains functional.

Define reporting clocks and incomplete-investigation procedures-- Specify whose awareness starts the 24-hour notification period, the minimum initial information, when the 30-day period begins, and when an interim report is acceptable because an investigation remains incomplete.

Replace detailed public incident reports with de-identified summaries-- Separate confidential information submitted to NIH from information intended for public disclosure. Public summaries should address the general nature of the event, risk, contributing factors, corrective actions, lessons learned, and oversight outcome without names, medical information, grant identifiers, proprietary details, or security-sensitive information.

Preserve confidential near-miss reporting-- Maintain a nonpunitive, de-identified learning pathway with clear limits on disclosure and enforcement use so that public-posting requirements do not discourage reporting.

Meeting minutes
Treat templates as content standards rather than fixed layouts-- Permit institutions to use established minutes formats when all required elements are present. Allow a public IBC roster to satisfy recurring documentation of member expertise when it contains sufficient information.

Define public-detail and redaction standards-- Specify the level of project detail required in public minutes and permit redaction of personal, medical, proprietary, grant-related, and security-sensitive information. Permit concise summaries of incidents, inspections, and delegated approvals.

Provide a reasonable posting period-- Replace “immediately after approval” with a defined period that accommodates preparation, redaction, quality review, holidays, and staffing constraints. Clarify whether public access to meetings is required or encouraged.

6. Other feedback relevant to this resource: Release complete implementation materials before the effective date-- Provide a standardized Biosafety Assurance template, applicability and review-pathway decision tools, model policies and charters, responsibility and reliance agreements, risk-assessment forms, worked examples, training materials, completed sample templates, redaction guidance, and guidance for shared or external IBCs.

Define the Biosafety Assurance process-- Specify required, conditional, and optional information; authorized signatories; submission and renewal procedures; completeness criteria; NIH review and response processes; approval scope and duration; material updates; reliance arrangements; and public versus confidential information. Preserve continuity during timely review of a complete renewal or transition submission.

Align authority with assigned responsibilities-- Define institutional leadership accountability and provide IBCs, BSOs, and biosafety-program leadership with authority, independence, access, escalation pathways, corrective-action mechanisms, and stop-work or suspension authority appropriate to their assigned functions.

Allocate responsibilities according to operational control-- Assign building systems, ventilation, emergency power, capital repairs, certification programs, and centralized maintenance to the responsible institutional functions rather than placing sole responsibility on investigators. Require biosafety training for PIs as well as supervised research personnel.

Clarify governance and conflicts of interest-- Define IBC establishment, charter authority, appointments, quorum, voting thresholds, recusals, remote participation, consultants, unaffiliated membership, suspension authority, and protection of independent biosafety judgment. Do not count a recused member toward the quorum required to act on the affected matter.

Address compliance costs and flexible institutional models-- Recognize appropriate biosafety costs, support workforce development and shared training, and permit shared personnel, contractors, consortium IBCs, external IBC services, and mutual-aid arrangements when authority, expertise, availability, reporting relationships, and accountability are documented.

Publish crosswalks and coordination guidance-- Explain the relationship of the final policy to the NIH Guidelines, federal high-risk research and DGOF or potential-DGOF oversight, Select Agent requirements, and other federal authorities. Identify review ownership, information-sharing expectations, and when oversight is cumulative or substitutive.

167. Tammy Bavaret, MS, PhD, RBP, CBSP, SM(NRCM)

I am responding: On behalf of myself

Name: Tammy Bavaret, MS, PhD, RBP, CBSP, SM(NRCM)

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Basic research, translational research, clinical research, recombinant and synthetic nucleic acid research, gene-editing technologies, and Biosafety Level 3 (BSL-3) operations

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's efforts to establish a comprehensive biosafety framework that extends beyond recombinant and synthetic nucleic acid research to include a broader range of biological hazards. Expanding the scope of oversight recognizes the evolving nature of biomedical research and provides an opportunity to apply a more consistent, risk-based approach across research activities.
However, I believe additional clarification is needed regarding the scope of covered research and the definition of "biohazard." The policy would benefit from more explicit guidance regarding activities involving genetically modified organisms, gene-editing technologies, attenuated agents, validated inactivated materials, self-amplifying RNA platforms, AI-assisted biological design, toxins, prions, and other emerging technologies. Clear examples should be provided to assist institutions in making consistent determinations regarding whether specific activities fall within the policy's scope.
I am also concerned that certain clinical research activities may inadvertently fall outside of biosafety oversight under the proposed framework. The draft policy appears to narrow clinical review triggers by focusing primarily on characteristics such as replication, integration, and shedding. While these are important considerations, they may not fully capture the potential biosafety implications of emerging gene-editing technologies or other biologically active investigational products. I encourage NIH to further evaluate whether additional oversight triggers are warranted to address these activities.
Finally, NIH should provide additional guidance regarding collaborative research, affiliates, leased facilities, community-based research sites, and multi-site clinical studies to ensure that oversight responsibilities are clearly assigned and consistently implemented.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support a tiered oversight model that aligns the level of review with the degree of biological risk. A risk-based framework allows institutions and oversight bodies to focus resources on activities that present the greatest potential impact to laboratory personnel, research participants, public health, agriculture, or the environment.
In general, local Institutional Biosafety Committees are well positioned to evaluate institution-specific factors such as personnel expertise, facility capabilities, local standard operating procedures,

occupational health resources, and training programs. These factors are often critical to an accurate risk assessment and are best evaluated at the local level.
Federal oversight should be reserved for activities involving novel or particularly consequential biological risks, including situations where standardized national review promotes consistency and public confidence. NIH review may be particularly appropriate for activities involving significant uncertainty, broad societal implications, or technologies that do not fit within established oversight frameworks.
To support consistent implementation, NIH should provide clear criteria and decision tools that help institutions determine when local review is sufficient and when federal review is warranted. Absent such guidance, there is potential for significant variability among institutions conducting substantially similar research.

3. Continued utility of Risk Groups: I strongly support continued use of Risk Groups as the starting point for biosafety risk assessment.
Risk Groups and Biosafety Levels serve distinct but complementary functions. Risk Groups characterize the inherent hazards associated with an organism, while Biosafety Levels represent containment practices and facility requirements selected following a comprehensive risk assessment. Maintaining this distinction remains important because containment decisions should be informed by the biological characteristics of the agent, nature of the modifications, routes of exposure, and specific experimental procedures.
At the same time, Risk Groups alone are not sufficient when evaluating genetically modified organisms. Modifications may increase, decrease, or otherwise alter risk in ways not reflected by the parent organism's Risk Group classification. Therefore, Risk Groups should continue to serve as the foundation of risk assessment while allowing institutions to incorporate additional factors related to genetic modifications, host range, pathogenicity, environmental persistence, transmissibility, and potential consequences of exposure.
Rather than replacing Risk Groups with Biosafety Levels, I recommend that NIH maintain the current approach in which Risk Groups inform the assessment process and Biosafety Levels are selected based on the outcome of that assessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The success of the policy will depend in part on its ability to encourage broad adoption beyond institutions that are formally required to comply.
NIH can promote voluntary compliance by providing practical implementation resources that reduce barriers to participation. Examples include model policies, biosafety assurance templates, institutional self-assessment tools, risk assessment templates, sample standard operating procedures, training materials, and decision trees.
NIH should also recognize and support reliance models that allow smaller institutions, community hospitals, physician practices, and independent research organizations to access qualified biosafety expertise through external IBCs and shared oversight arrangements. Many organizations lack the resources to maintain a fully independent biosafety program but remain committed to implementing high-quality biosafety practices.
Additional incentives could include educational outreach, publicly available training resources, recognition programs, and technical assistance opportunities that help organizations align with NIH expectations even when compliance is voluntary.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I support NIH's effort to standardize incident reporting and meeting documentation. Consistent reporting structures can improve trend analysis, facilitate lessons learned, and promote greater transparency across the research community.

For the Incident Reporting Template, I recommend NIH:

• Clearly distinguish reportable incidents from events that may be managed locally.
• Define key reporting terms such as exposure, containment breach, laboratory-acquired infection, near miss, and significant incident.
• Include fields that capture root-cause analysis, corrective actions, and preventive measures.
• Provide guidance regarding protection of confidential, proprietary, personnel, medical, and security-sensitive information.
• Clarify whether all submitted information will be made publicly available and, if so, what information may be redacted.

For the Meeting Minutes Template, I recommend NIH:

• Allow flexibility for documenting discussions in a manner appropriate to committee complexity.
• Clarify expectations for documenting dissenting opinions and conflict-of-interest recusals.
• Clearly distinguish required elements from optional meeting notes.
• Provide guidance regarding management of confidential information and proprietary research details included in meeting records.

The templates should facilitate meaningful documentation while minimizing unnecessary administrative burden.

6. Other feedback relevant to this resource: The implementation resources provided are a valuable starting point, but additional guidance will likely be necessary to support successful adoption across the research community.

The areas where further guidance would be most beneficial include:

• Clinical research oversight and applicability.
• Gene-editing technologies and genome engineering platforms.
• Emerging biotechnology applications that may not fit existing categories.
• Delegated review mechanisms and risk-based oversight pathways.
• Externally administered IBC models and reliance agreements.
• Institutional responsibilities under Biosafety Assurances.
• Multi-site and collaborative research oversight.
• Incident reporting expectations and public disclosure requirements.
• Risk assessment methodologies for modified organisms and novel constructs.
• Transition planning for currently compliant institutions.

I also recommend that NIH develop a comprehensive implementation toolkit that includes examples, frequently asked questions, decision trees, sample policies, risk assessment templates, and illustrative case studies. These resources would significantly improve consistency and reduce implementation challenges across institutions of varying size and complexity.

Additional comments/suggestions are provided in the attachment as well.

Uploaded File: Final-Comments-on-the-Draft-NIH-Biosafety-Policy.docx

Description: Additional Comments on the Draft NIH Biosafety Policy

Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Thank you for the opportunity to provide comments on the Draft NIH Biosafety Policy for Research Involving Biohazards.

As a Certified Biological Safety Professional (CBSP), Institutional Biosafety Committee (IBC) Chair, Biosafety Consultant, and former Assistant Director of Biosafety and Biocontainment Operations/Institutional Biosafety Officer, I have more than a decade of experience supporting biosafety and biosecurity programs, managing IBC operations, conducting biological risk assessments, overseeing high-containment laboratory programs, and advising research institutions on compliance with federal biosafety requirements. My experience includes oversight of basic research, translational research, clinical research, recombinant and synthetic nucleic acid research, gene-editing technologies, and Biosafety Level 3 (BSL-3) operations. I currently serve as Chair of Institutional Biosafety Services for externally administered IBCs, where I lead reviews of clinical and non-clinical research protocols and support institutions navigating complex biosafety oversight requirements.

I support NIH's efforts to modernize biosafety oversight and establish a comprehensive framework that protects research personnel, research participants, the public, and the environment while enabling responsible scientific advancement.

Overall, I encourage NIH to further refine the policy to improve consistency, clarify applicability, strengthen institutional accountability, and ensure oversight requirements remain proportionate to actual biological risk. Particular attention should be given to clinical research, implementation logistics, externally administered IBC models, and the operational challenges institutions will face when transitioning to the new framework.

1. Scope and Applicability

The policy would benefit from greater clarity regarding which activities, sites, institutions, and research types fall within its scope.

I recommend that NIH provide:

- A clear applicability matrix identifying activities requiring no review, administrative review, delegated review, full IBC review, or NIH review.
- More precise definitions of covered research, institutional sponsorship, affiliates, leased facilities, collaborative research, and off-site activities.

- Additional examples addressing common research activities such as work with established cell lines, transgenic animals, validated inactivated materials, plant pathogens, agricultural research, and veterinary research.
- Clear guidance regarding how NIH oversight intersects with requirements from other federal agencies.

Institutions need practical decision-making tools that can be applied consistently across diverse research environments.

2. Clinical Research Oversight

One area that warrants substantial clarification is the treatment of clinical research.

Under the current NIH Guidelines, IBC oversight applies broadly to many clinical studies involving recombinant or synthetic nucleic acid technologies. The draft policy appears to narrow oversight considerably by limiting review triggers primarily to specific characteristics such as replication, shedding, or integration. As written, this creates uncertainty regarding whether certain clinical products would remain subject to biosafety review despite presenting meaningful biological risk.

I encourage NIH to develop a dedicated clinical research section similar in scope and detail to the current NIH Guidelines rather than addressing clinical oversight through a limited subsection embedded within broader laboratory research categories.

Particular clarification is needed regarding:

- Whether the clinical research provisions are intended to be the sole basis for determining IBC review requirements for clinical studies.
- The relationship between clinical review categories and delegated review pathways.
- Oversight expectations for multicenter studies.
- Oversight endpoints when biological activity may continue after final administration of a product.
- Circumstances under which institutions may apply additional biosafety review based on local risk assessments.

The biosafety implications of clinical research frequently extend beyond the clinical setting and may involve exposure risks to healthcare workers, laboratory personnel, caregivers,

family members, and communities. The policy should ensure these considerations are addressed consistently.

3. Gene Editing and Emerging Technologies

The draft policy appears to focus heavily on integrating vectors while providing limited discussion of modern genome-editing approaches.

I recommend adding gene editing as an independent consideration for oversight rather than relying solely on integration-based triggers.

Technologies such as:

- CRISPR systems,
- Base editors,
- Prime editors,
- Non-homologous end joining approaches,
- Self-amplifying RNA systems, and
- Future genome-engineering platforms

may create significant and lasting biological effects even when they do not involve traditional integration events.

Oversight decisions should be informed by biological function, potential exposure consequences, and residual risk rather than by platform classification alone. The final policy should also be flexible enough to accommodate emerging technologies that may not fit neatly within current regulatory categories.

4. Risk Assessment Framework

I support continued use of Risk Groups (RGs) as the starting point for biosafety risk assessment.

Risk Groups describe the hazard characteristics of an organism, whereas Biosafety Levels (BSLs) represent containment measures selected after completion of a risk assessment. Maintaining this distinction is important because containment decisions should flow from the characteristics of the agent and proposed work rather than serve as the starting point for evaluation.

Additional guidance would be valuable for:

- Genetically modified organisms.
- Attenuated strains.
- Validated inactivated materials.
- AI-designed sequences.
- Gene-drive technologies.
- Toxins.
- Prions and self-aggregating proteins.
- Novel or proprietary constructs.

Standardized risk assessment templates and examples could help improve consistency across institutions and reduce variability in oversight determinations.

5. Institutional Accountability and Program Infrastructure

The success of the policy will depend heavily on institutional capacity.

NIH should explicitly identify the responsible institutional authority accountable for biosafety program implementation and ensure institutions maintain sufficient infrastructure to support compliance.

Minimum expectations should address:

- Professional biosafety expertise.
- Administrative support.
- Committee operations.
- Training programs.
- Records management.
- Occupational health support.
- Incident response capabilities.
- Compliance monitoring activities.

I also encourage NIH to recognize that institutions vary significantly in size and complexity and should permit documented reliance arrangements, shared resources, and qualified external support when responsibilities and authorities are clearly defined.

6. Institutional Biosafety Committee Operations

The policy would benefit from a clearer separation between committee governance requirements and substantive biosafety responsibilities.

Additional clarification should address:

- Quorum requirements.
- Management of conflicts of interest.
- Delegated review procedures.
- Required expertise.
- Voting standards.
- Authority to suspend or withdraw approvals.
- Emergency response authorities.
- Risk-based inspection frequencies.

In particular, members recused due to conflicts of interest should not be counted toward decision-making quorum for the affected protocol. NIH should also consider providing examples of acceptable delegated review practices to promote consistency among institutions.

7. Incident Reporting and Public Transparency

I support the goal of increasing transparency and improving biosafety learning across the research community. However, reporting requirements should be structured in a manner that encourages, rather than discourages, timely reporting.

The final policy should:

- Clearly distinguish incidents requiring NIH notification from events that can be managed locally.

- Define key terms such as exposure, containment loss, near miss, laboratory-acquired infection, and significant incident.
- Clarify reporting timelines and investigative expectations.
- Establish appropriate redaction standards to protect personal, medical, confidential, proprietary, and security-sensitive information.

Consideration should also be given to the possibility that mandatory public posting of incident reports could inadvertently discourage prompt reporting if individuals fear public identification, reputational consequences, or misinterpretation of events that ultimately pose little risk. Balancing transparency with appropriate privacy and security protections would better support a strong reporting culture.

8. Clarification of Key Operational Terms

Several terms serve as major triggers for oversight but are not currently defined with sufficient precision.

I recommend that NIH provide clear operational definitions and examples for:

- Shedding.
- Replicating products.
- Higher-risk manipulations.
- Containment failures.
- Integrating versus gene-editing technologies.
- Adventitious agent contamination.
- Environmental release.
- Biological exposure.

Without standardized definitions, similar research may receive substantially different oversight determinations at different institutions, creating inconsistency across the research enterprise.

9. Externally Administered IBCs

Many community hospitals, physician practices, rural research sites, independent research organizations, and smaller institutions rely on external IBCs because maintaining a fully independent biosafety program is not operationally feasible.

The final policy should clearly permit reliance arrangements that allow qualified external IBCs to:

- Support Biosafety Assurance requirements.
- Provide biosafety policies and procedures.
- Maintain required records.
- Host required public-facing postings.
- Coordinate reporting activities.
- Assist with compliance monitoring.
- Provide risk assessment expertise and regulatory support.

Institutions should remain accountable for compliance while retaining the flexibility to leverage qualified external expertise.

Such an approach would improve consistency, reduce administrative burden, increase access to qualified biosafety professionals, and facilitate implementation across diverse institutional settings.

10. Implementation Timeline

The proposed implementation timeline may underestimate the scope of institutional changes required.

Institutions will need to:

- Identify newly covered activities.
- Establish or revise Biosafety Assurances.
- Update policies and procedures.
- Train researchers and staff.
- Expand committee capacity.
- Implement recordkeeping systems.

- Revise reporting workflows.
- Develop or update risk assessment processes.

I therefore recommend a phased implementation strategy with at least 12 months between publication of final guidance and full compliance requirements.

This transition period should include published templates, implementation resources, examples, decision tools, and frequently asked questions before institutions are expected to comply with new requirements.

Conclusion

I support NIH's objective of creating a modern, risk-based biosafety oversight framework. I encourage NIH to clarify the policy's scope, strengthen implementation guidance, ensure consistent oversight of clinical research and emerging technologies, provide practical accommodations for externally administered IBC models, and align oversight obligations with demonstrable biological risk.

From my experience leading institutional biosafety programs, managing IBC operations, conducting risk assessments, and supporting both academic and clinical research environments, I believe these enhancements would improve consistency, strengthen biosafety oversight, and promote successful implementation across the diverse institutions conducting biomedical research today. Ultimately, a clear, practical, and risk-based policy framework will better support both scientific advancement and public trust in the research enterprise.

168. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Other

Type of Organization - Other: Academic Medical Research Institution

Role: Other

Role - Other: Regulatory Compliance

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

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Recommendations to the National Institutes of Health Office of Science Policy

We support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. **Purpose and program identity**

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. **Scope definitions and implementation**

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide

coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Request for consideration. Current definitions of genetic modification generally center on techniques or experiments that cause heritable or persistent changes to the genetic material of a host cell or organism; that is, genomic DNA, or genomic RNA for certain viruses. However, the proposed definition includes nucleic acids that "can be transcribed or translated," which could classify many established vaccine technologies as genetic modification even when the platform does not alter the recipient's genome. NIH should consider revising the definition to distinguish genome-altering technologies from transient expression or translation of introduced nucleic acids. NIH should also clarify whether nonintegrating messenger RNA, self-amplifying RNA, nonintegrating DNA, and other transient vaccine platforms are intended to fall within scope; explain how persistence, integration potential, heritability, and biological function affect classification; and provide examples identifying when vaccine research requires IBC review, documentation only, or no review. Any expanded definition should be scientifically justified, risk-based, and coordinated with relevant FDA requirements to avoid duplicative or inconsistent oversight.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. **Institutional accountability and Biosafety Assurances**

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether

separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

1. **IBC establishment functions and operations**

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

2. **Investigator responsibilities and voluntary reporting**

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

3. **NIH implementation responsibilities and coordination**

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

4. **NIH review and containment determinations**

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

5. **IBC review pathways and clinical oversight**

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

6. **Risk assessment and specialized materials**

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

169. Ryan Lisk

I am responding: On behalf of myself

Name: Ryan Lisk

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Safety Professional

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious diseases; microbiology; virology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope requires further clarification, as biohazards go beyond just those posing risk/potential risk to human health. Given the exclusion of applicability to plants and animal-only pathogens, there would need to be policies separate that address those. Will those be coming from the USDA and/or APHIS? These policy silos are not mutually exclusive and it may be dangerous to treat them as such.

Is known or suspected/potential risk the necessary criteria for all research subject to this policy? If we are excluding animal-only pathogens, this would seem to confuse the requirement for IBC membership to include animal-containment SME, incident reporting for research animals, and, expressly-referenced zoonotic agents. Further clarity is needed to specify intent, animal-related procedures and environmental consequences are exempt unless zoonotic or genetically modified.

Clean and comprehensive definitions of what this policy refers to/covers as biological agents, BBPs, environmental samples, and prions. As an example, the stated definition of a “biological agent” excludes non-pathogenic organisms, animal-only pathogens. This is confusing, with respect to later policy references to “biological agent” when discussing RG1 materials, zoonotic agents, genetically modified agents,, environmental impacts, and organisms not currently known to cause disease in humans. As currently written, clarification is needed with regard to whether the aforementioned is exempt from the policy and what other policies now or in the future will address these.

Broader application of institutions receiving NIH funding. As currently worded, it seems as though the research that is not NIH-funded is still under the purview of this policy by proxy of an institution receiving NIH-funding elsewhere. This is an important distinction, in terms of bandwidth considerations for any direct and any indirect support stakeholders and considering what additional constraints this implicates.

Research involving plants - policy references environmental containment, ecological risk assessment, and

GDMOs intended for environmental release. This further necessitates capturing plants as part of this policy or having a separate policy to address this category of research.

Research in clinical settings - can the BSO and/or IBC establish appropriate review and survey requirements? This policy should allow autonomy and flexibility to accommodate differences in physical environment, workflows, and risk mitigation measures that often vary widely from the typical research lab environment. A separate definition of clinical research that falls under this policy would be useful in clarifying the review process. Under section IV-2, clinical research involving deliberate biohazard administration to "one" human research participant should be clarified with respect to this being a limit for the number of participants before obtaining approval.

Roles and responsibilities - for the BSO vis-a-vis "periodic inspection" should be clarified as to be prescribed in an institution's Biosafety manual/IBC Charter or as part of this policy.

Administrative burden associated with review cycle may be significant, as currently articulated. Encourage the NIH to consider administrative burden and clarify "periodic review" of research. This is too vague.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Federal policy is clearly necessary to provide the framework. That's why clarity in this policy is crucial. Localized governance by letting the Biosafety professionals and the IBC members should maintain appropriate risk assessments and provide the best local oversight of controlling biological risk. This seems to disenfranchise that core principle by a fair margin.

Initial requests for NIH to lower containment below BSL-2 for research involving GDMOs - will the NIH publish the outcomes of its review for higher-risk research involving emerging, novel, or zoonotic agents for which RG classification or minimum containment level is not currently established in the BMBL? If such determination is established and it is published, will institutions still be required to submit individual protocols for NIH review or would that circumvent that need?

Full IBC review required for research involving toxins listed as Select Agents. Clarify if the NIH will accept or override all exemptions and permissible toxin amounts, as defined under the Federal Select Agent Program, whether inactive toxin derivatives or isolated subunits are considered "toxins," and whether nucleic acids encoding toxins are considered toxins and/or both.

Section IV-3 - for delegated review, must this include voting members of the IBC or can it include non-voting members, as defined by the institution's IBC? Can the institution define the process for notification, when granted, by delegated review - for reporting to the IBC?

3. Continued utility of Risk Groups: Used as a basis and appropriate risk assessments conducted locally to determine requests for adjustment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): This is requiring further clarification as to what applies. If the idea is make this a best practice regardless, more teeth should be added to that effect - including incentives for compliance.

Compliance violations at any BSL/ABSL must have clarity on what should be reported.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Requiring minutes to document individual's SME is duplicative, if required to publish a roster with that information already. Can we clarify if the roster availability satisfies this?

Policy should clarify expected level of detail for project descriptions - while protecting nature of the proprietary, confidential, or otherwise sensitive information.

Summaries of incidents should not contain identifiable information that is made public. People and organizations may insinuate this information, without names, provided the level of detail being required. Incidents should only be shared with the National Biosafety Data and Safety Analysis Center. Public posting of incidents will discourage proper reporting.

Scope of incident reporting should focus on events relative to Biosafety and Biosecurity risks - such as exposure to a hazard; release or potential release, lab equipment failures that result in exposure or release, and significant near misses involving biohazards.

6. Other feedback relevant to this resource: Succinct workflow diagrams and charts outlining roles and responsibilities, making determinations about what research applies, and when to report incidents would be helpful. Tip sheets and short guidance tools for researchers and Biosafety professionals alike would be extremely valuable complements.

170. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Organizational Official

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Neurological diseases, virology, cancer, and immunological diseases: both basic research and clinical studies

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: a. Inclusion of native pathogens, biological toxins, and pathogenic prions is appropriate because these agents present hazards that merit committee oversight. Our institution previously constituted and currently maintains a separate Biohazard Committee for this purpose. The revised Guidelines should explicitly permit two IBCs per institution to permit specialization between recombinant nucleic acids and the native pathogens, etc. included in the new scope, and to accommodate the expanded workload. The acronym GDMO for "gene drive modified organism" must be expanded in the policy's definition of "gene drive." A clear statement on whether plant research is intentionally being removed from NIH oversight, whether another agency (e.g., USDA) is assuming responsibility, or whether a separate policy is forthcoming would avoid a gap in oversight on this topic.

b. Oversight of clinical research is appropriate, given the development of nucleic acid-based agents that could affect not only patients but also their sexual partners, health care personnel who administer them, and families of the patients who receive them. Arguably the most important contribution of our IBC to clinical research, however, has been our scrutiny of Informed Consents, which have frequently been incomplete in their description of risks. An IBC collects and further develops expertise in gene transfer that may exceed that of an IRB charged with addressing many other issues. In our experience, IBC consent reviews are appreciated by the IRB because they provide assurance that all relevant risks have been considered and addressed. The Guidelines policy should explicitly encourage review of Consent documents by the IBC.

c. The draft policy's definition of "Genetic Modification" expands the oversight scope substantially with the following phrase: "The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical, or radiological means."
This phrase can be construed to include both embryological and pluripotent stem cells that are differentiated by passaging in specific environments, as well as cells that are deliberately subjected to mutagenic chemicals and ionizing radiation. Cells mutated by chemical or radiation mutagenesis and

stem cells that have been differentiated are unlikely to pose serious risks comparable to those of recombinant agents or native pathogens. We recommend that the Guidelines state that the differentiation of stem cells by passaging and routine chemical or radiation mutagenesis are outside the scope of the policy. Alternatively, provide examples and a clear risk-based threshold for when such work comes within the IBC scope.

d. Because the draft definitions of “biohazard” and “genetic modification” are so broad, activities that have long been regarded as negligible in risk could be construed as within scope, substantially increasing IBC workload without a corresponding gain in safety. The policy should include an explicit list of low-risk activities that are excluded from oversight (i.e. antisense oligonucleotides), or state clearly that institutions may establish and document their own exclusion criteria.

e. The draft extends the policy to non-NIH-funded research conducted at any institution that receives NIH funding. The current Guidelines contain a similar institution-wide condition, but only for recombinant or synthetic nucleic acid research; the draft applies it to all biohazards, including wild-type pathogens. The new Guidelines should clarify how this provision applies to industry- or privately sponsored work (i.e., sponsors of gene therapy agents in multisite clinical trials), to collaborative work conducted at other sites, and should avoid duplicative or conflicting review.

f. The proposal eliminates the dedicated human gene transfer category and instead relies on product characteristics (products capable of shedding, replicating, or integrating; higher-risk administration or manipulation procedures; and administration of RG2 or higher wild-type agents). We support a characteristic-based approach, but the Guidelines should state explicitly whether nucleic acid-based clinical products that do not meet these descriptors (for example, non-replicating, non-integrating nucleic acid therapeutics) are within scope. The policy should also preserve the IBC review of clinical protocols and other related documents to take maximum advantage of the IBC’s expertise.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): a. The requirement for quadrennial (or more frequent) certification of compliance by an institutional official and its verification by a federal oversight agency is not well described. The policy, as written without details, would enable a crippling and disproportionate institutional penalty for non-compliance regardless of severity or risk, without clear criteria and without opportunity for institutional appeal or remediation. A mechanism for evaluation of compliance that explicitly does not depend on the judgement of a single federal official, and that provides opportunity for appeal and remediation before cessation of federal support should be described in detail.

b. In Section III-B. “The institution shall establish an IBC to meet the criteria outlined in this policy.” The draft Guidelines acknowledge the possibility of a commercial external IBC by the phrase “and/or has an externally administered IBC” (Section IIIA bullet 2). The enlarged scope of oversight, the dependence on BMBL standards for risk assessment, and the requirements for incident reporting make it inconceivable to us that an external commercial IBC could accurately perform these functions. The BMBL places great emphasis on physical and engineering safety facilities, signage, and other laboratory-specific practices. These facilities and practices cannot be evaluated remotely. The more hazardous nature of native pathogen research compared to most recombinant or synthetic nucleic acid research strengthens the rationale for prohibition of external IBCs under the revised Guidelines.

c. The draft eliminates the simultaneous-notification category (current Section III-E). We recommend retaining an administratively exempt category for the lowest-risk research (for example, BSL1 work with well-characterized, non-hazardous materials) so that IBC time can be focused on research that warrants it. Delegated review, although helpful, still requires an IBC action on every protocol, and without a lower tier the expanded scope will substantially increase workload.

d. The proposal asks for a continuously updated IBC roster, IBC minutes, incident reports, biosafety training records, and it requires public posting of minutes and incident reports. We support transparency, but public posting of members' personal information and incident details creates privacy, personal safety, and security risks for members, investigators, and institutions. The Guidelines should specify which information must be public versus that provided only to the NIH, provide standard redaction criteria, and consider offering an NIH-hosted platform in place of separate institutional postings.

3. Continued utility of Risk Groups: a. Risk groups are very useful for native pathogens. Risk groups could be defined for specific viral vectors and pathogenic proteins. These would supplement the BMBL criteria. It should be the applicant's burden of proof to convince the IBC that their specific modifications of pathogens reduce the risk group or, in other ways relax the safety protocols by which agents in their pre-modification risk groups are handled.

b. The BMBL criteria for Biosafety Levels are highly dependent upon physical facilities, signage, documentation of procedures, practices, and laboratory visitors. As noted above, the Biosafety Level procedures could be followed and documented properly only with a local IBC.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): a. Our organization is funded by the NIH; hence compliance is required. We recommend free access to NIH-provided resources, including model SOPs, risk-assessment forms, training modules, and the incident-report and meeting-minutes templates, together with technical assistance from NIH OSP, to assist IBCs at all institutions in performing their duties regardless of NIH funding.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: a. The 24-hour (or "as soon as the institution becomes aware") NIH notification, followed by a complete report within 30 days, seems reasonable for confirmed laboratory-acquired infections and serious events. However, "potential LAI," "release with community risk," and "compliance violation" need operational definitions. As written, any compliance violation, however minor, could trigger a 24-hour report. We recommend that only significant violations (those involving actual or potential exposure or release) require 24-hour notification, and that minor violations corrected locally be documented by the IBC and available to NIH on request. NIH should also provide a reporting mechanism that is available outside business hours. Allowance must be made for delays until the IBC is informed.

b. Public posting of incident reports should be limited to what is necessary. Personal and medical information of employees and details that would reveal facility vulnerabilities must be redacted, and the template should separate public-facing fields from NIH-only content. Posting should occur only after investigation and any personnel actions are complete. For this reason, the 30-day timeframe appears to

be short. We believe that public posting of incidents for 5 years is counterproductive, since it would obscure the ability of institutions to correct problems over a much shorter period.

6. Other feedback relevant to this resource: a. Our institution will need time to revise and re-engineer the digital portal by which applications are created by the investigator and received and reviewed by the IBC and other committees that might have regulatory jurisdiction (IACUC and IRB). We request a one-year (or longer, rather than six-month), implementation grace period between adoption of the revised Guidelines and enforcement of compliance.

b. NIH should publish, before the compliance date, a list of frequently asked questions, a model institutional triage procedure, and model risk-assessment forms for investigators and IBCs.

c. Because no covered research may proceed until NIH approves the institution's Biosafety Assurance, NIH should publish review timelines and allow research to continue under the current framework during the transition and while the Biosafety Assurance renewal is pending.

d. Implementation will require additional IBC staff time and expertise. NIH should clarify that these are allowable administrative costs and facilitate access to such expertise, for example through a directory of qualified consultants who can serve as ad hoc advisors to local IBCs, while leaving local IBCs responsible for oversight of facilities and practices.

e. NIH should provide guidance on coordinating IBC review with IRB and IACUC review and with other federal programs to facilitate institutional compliance. This will also result in a smooth and streamlined workflow.

171. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/14/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: "Organisms" is too broad of a category. Not all genetically modified organisms need oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Seems like a lot more paperwork and slowdown of research.

IBCs should be for 5 years, and current approvals should be grandfathered in.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Don't need to report incidents on a public-facing website.

172. Dartmouth College

I am responding: On behalf of an organization

Name: Emily Burlij

Name of Organization: Dartmouth College

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Biosafety-RFI-Comments_20261014.pdf

DARTMOUTH
Office of the Provost

Dean R. Madden, PhD
Vice Provost for Research
Professor of Biochemistry & Cell Biology
dean.madden@dartmouth.edu

October 14, 2026

To Whom It May Concern:

Thank you for providing the opportunity to comment on the National Institutes of Health (NIH) proposed biosafety policy for research involving biohazards. While we appreciate NIH's goal to modernize existing oversight of biohazards research and ensure the safety of the public, we urge NIH to revise or proceed cautiously with several provisions.

In particular, NIH requested input on the continued use of risk groups as a baseline for risk assessment. Dartmouth would encourage NIH to continue using existing risk groups as they remain well understood and very useful as a starting point in succinctly categorizing biological agents. Not using existing risk groups would greatly increase inconsistency and confusion between research institutions.

NIH must continue to provide clarity on the reference points for risk groups. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) defers to existing NIH Guidelines, which are thus the primary source for risk group information. Consistent with the comments above, we also believe that any new policy should remain aligned with the current Guidelines. If any modifications are made, they should be designed to enhance alignment with international risk-group classifications. Whatever system is ultimately applied, NIH should also consider providing the updated list of approved risk groups or sources on its website.

Aside from these general suggestions, we also ask NIH to consider changes to specific sections as outlined below:

<u>Section II. General Definitions</u>

- Dartmouth recommends removing "passaging" from the second prong of the definition of genetic modification. Spontaneous mutation occurs in all maintained cultures whether or not the changes are deliberately selected.
- NIH should not include "clinical settings" in the definition of "laboratory research." First, its inclusion in the definition is confusing, given that later sections separate such research from other settings. Second, this would include clinical laboratories, for which additional oversight would not provide a meaningful improvement over the current process. These laboratories are typically overseen by strict accreditation standards, and further IBC oversight would add confusion without added benefit.

<u>Section III-B: Institutional Biosafety Committees (IBC) Responsibilities</u>

NIH should reconsider requiring institutions to post all incident reports on a public webpage, as not all incidents result in a public impact. Minor incident reports are key in understanding and

acting on institutional safety trends as a means of avoiding more significant incidents. Unfortunately, requiring all incident reports to be publicly posted will discourage reporting of minor incidents by researchers and may therefore have a paradoxical effect of decreasing safety. Only NIH-reportable incidents should be publicly posted, because those are the incidents with potential impacts on health.

Section IV-2: Research Requiring IBC Approval

- Research involving genetically modified cells should not be included in this section if the cells are not biological agents. Otherwise, a full IBC review would be required for lower risk cell lines such as common noninfectious cells, while only delegated review would be required for some higher-risk agents.
- NIH should further clarify that the statement that "primary cells that may be contaminated by adventitious agents" means primary cells that are known or reasonably suspected to contain other materials described in Section IV-2. All primary cells "may" contain adventitious agents and would therefore require full IBC review, while most adventitious agents themselves are RG2 and would only require delegated review.
- NIH should also provide greater clarity for the phrase "capable of shedding." Most products exhibit some form of shedding. It would be helpful to delineate more specific criteria, such as specifying if this means only intact and viable product, if it must be based on data for each individual product, and if preclinical data can be used. Most relevant clinical trials include shedding assessment, therefore agent-specific shedding data from humans are often not yet available, and most assessments are made by PCR, which does not indicate viability.

Section IV-3: Research Requiring Individual or Subgroup IBC Approval

NIH should better define what constitutes a "well characterized" cell line, or, alternatively, what would constitute a cell line that is insufficiently characterized for review under this section. Otherwise, institutions will have difficulty in assessing which cell lines require a deeper review process.

Thank you again for the opportunity to comment.

Sincerely,



Dean R. Madden, PhD
Vice Provost for Research
Professor of Biochemistry & Cell Biology

173. Manjunatha Krishnoji

I am responding: On behalf of myself

Name: Manjunatha Krishnoji

Name of Organization: Syngene International

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biotech research CRO

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's effort to broaden biosafety oversight beyond recombinant nucleic acid research. One area that may need additional consideration is the management of biologically active recombinant products.

In my experience, risk assessments are often focused on the source organism, host system, vector, and genetic modification. However, some products generated from low-risk systems can themselves present significant occupational health hazards. Examples may include high-potency monoclonal antibodies, immune-modulating proteins, cytokines, growth factors, oncogenic proteins, and other biologically active molecules.

For these products, the hazard is not necessarily related to the Risk Group classification of the host organism. The concern may instead be related to the biological activity, potency, mechanism of action, and potential health effects of the expressed product.

I believe NIH should consider whether biologically active recombinant products that have the potential to cause adverse health effects should be specifically recognized within biosafety risk assessment requirements. This would help address a potential gap in oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A risk-based approach is appropriate. For biologically active recombinant products, local institutional review may be the most practical approach because the hazards are often product-specific and require detailed knowledge of the research activity.

NIH may consider providing guidance on when review by the Institutional Biosafety Committee (IBC) and Biosafety Officer (BSO) is expected, even when the work involves Risk Group 1 organisms.

3. Continued utility of Risk Groups: Risk Groups remain useful and should continue to be part of the assessment process. However, Risk Group classification alone may not fully capture the potential hazards associated with biotechnology-derived products.

A product expressed in a low-risk host may still pose a significant occupational health concern because of its biological activity. Therefore, risk assessments should consider both the characteristics of the organism and the hazard potential of the expressed product.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The policy would benefit from practical guidance documents, case studies, and examples that demonstrate how institutions can evaluate biotechnology-derived products with significant biological activity.

Many organizations outside NIH-funded research may be willing to adopt the framework if clear implementation guidance is available.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting template could include consideration of whether an incident involved exposure to a biologically active recombinant product and whether occupational health follow-up was required.

Capturing this information may help institutions better understand and learn from these types of events.

6. Other feedback relevant to this resource: Additional guidance would be helpful in the following areas:

Assessment of biologically active recombinant products.
High-potency monoclonal antibodies and related molecules.
Cytokines, growth factors, immune modulators, and oncogenic proteins.
Determining when IBC or BSO review is needed.
Examples of exposure assessment and control measures for biotechnology-derived products.

NIH may consider clarifying that biologically active recombinant products with significant occupational health implications should undergo review by Biosafety Officers (BSOs) and, where appropriate, Institutional Biosafety Committees (IBCs), as these groups possess the specialized expertise necessary to evaluate biological hazards that may not be readily identified through conventional Health and safety or industrial hygiene assessments alone.

174. Wayne State University

I am responding: On behalf of an organization

Name: Richard Pearson

Name of Organization: Wayne State University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: WSU_IBC_NIH_Biohazard_Policy_Comments.docx

Description: WSU IBC NIH Biohazard Policy Comments

DATE: October 15th, 2026

TO: NIH OSP

FROM: Wayne State University, Institutional Biosafety Committee
Detroit, MI

RE: WSU IBC Comments on the Draft NIH Policy for Biohazard Research

Purpose

This memo provides a consolidated list of comments that the WSU Institutional Biosafety Committee (IBC) have provided for submission in response to the request for feedback on the NIH draft policy on biohazard research. The comments support modernization of biosafety oversight while requesting clearer scope, objective review criteria, workable transparency protections, coordinated governance, and a realistic implementation framework.

Section 1. Scope, Definitions, and Applicability

Comment

The draft policy includes several terms that lack sufficiently objective applicability criteria, including *"biomedical research," "potential risk to human health," "well-characterized cell lines," "primary cells," "toxins,"* and *"genetic modification."* As written, these terms may be interpreted differently across institutions, resulting in inconsistent implementation and uncertainty regarding which activities require IBC oversight.

NIH should provide clear definitions, exclusions, examples, and decision-making tools that enable institutions to determine consistently whether an activity falls within the scope of the policy. Additional clarification is needed for common research activities and materials, including cell culture systems, toxins, genetically modified organisms, validated inactivated materials, and other activities for which applicability may not be readily apparent.

Rationale

A central objective of the proposed policy is to ensure appropriate oversight of research activities that may pose a meaningful risk to human health, animal health, agriculture, or the environment. However, broad or subjective applicability criteria may result in routine low-risk activities being brought under IBC review despite being effectively managed through existing institutional safety, training, inspection, and compliance programs.

Expanding IBC oversight in this manner may divert committee time and expertise away from research involving significant biological hazards, where biosafety review provides the greatest benefit. More precise applicability criteria would improve consistency across institutions, reduce unnecessary administrative burden, and ensure that IBC resources remain focused on activities presenting meaningful biosafety concerns.

Section 2. Transgenic Animals and Other Research Models

Comment

The draft policy does not clearly explain how certain categories of research, including some transgenic animals and other genetically modified research models, align with the stated objective of overseeing activities that may pose a risk to human health, animal health, agriculture, or the environment. As written, it is unclear whether oversight is intended to be triggered by demonstrated biological risk or by broad categories of biological manipulation.

NIH should clarify the rationale and review expectations for transgenic animals and other commonly used research models that may present minimal biological risk. The final policy should provide additional guidance, examples, and appropriate exclusions that distinguish activities requiring formal biosafety review from those whose hazards are negligible, well understood, or effectively controlled through established laboratory practices.

Rationale

Many commonly used research models, including certain transgenic insects, established transgenic animal strains, laboratory-adapted organisms, and other well-characterized genetically modified systems, may present little or no meaningful biosafety risk despite potentially falling within broadly defined categories covered by the policy.

Similarly, other activities, such as work involving biological toxins without clearly defined risk thresholds, may create uncertainty regarding whether oversight is intended to be based on actual hazard or merely the presence of a particular material or technology. Without clearer risk-based criteria, institutions may devote substantial review effort to activities with minimal biosafety implications while applying inconsistent standards across institutions.

A framework that more clearly links oversight requirements to demonstrable biological risk would improve consistency, preserve IBC resources for higher-risk research, and better align implementation of the policy with its stated public health and biosafety objectives.

3. Institutional Assurance, Governance, and Authority

Comment

The draft policy appears to make NIH approval of an institutional assurance a prerequisite for conducting covered research; however, the requirements for assurance approval, maintenance, renewal, institutional governance, and compliance accountability are not clearly defined. The policy should provide greater clarity regarding assurance content, approval criteria, review timelines, continuity of research activities, and institutional responsibilities.

NIH should establish transparent standards for assurance review and approval, clearly define institutional roles and authorities, and provide mechanisms that allow research activities to continue during assurance renewals, updates, or federal review periods.

Rationale

Institutions must have a clear understanding of the requirements necessary to establish and maintain compliance. Without defined approval criteria and timelines, institutions may face uncertainty regarding whether research activities can proceed, continue, or be modified. Delays in assurance approval or differing interpretations of institutional responsibilities could create inconsistencies among institutions and unnecessarily disrupt research operations. Clearly defined governance expectations would promote uniform implementation while strengthening institutional accountability.

4. Transparency, Public Posting, and Redaction

Comment

The draft policy would substantially expand requirements for public posting of IBC-related information, including committee records, procedures, incident information, membership information, and other institutional documents. While transparency is an important objective, the current proposal does not clearly define limits on public disclosure or establish consistent standards for protecting personal information, proprietary information, security-sensitive information, or information associated with ongoing investigations.

NIH should establish standardized national redaction requirements, clearly define what information must be publicly disclosed, and provide exclusions or protections for information that could compromise privacy, security, intellectual property, research integrity, or personal safety. The final policy should carefully balance public transparency with the need to protect individual researchers, biosafety personnel, institutional officials, and IBC members from unnecessary exposure through publicly accessible records.

Rationale

Transparency requirements should strengthen public trust without discouraging candid reporting, committee participation, or institutional self-assessment. Without consistent standards, institutions may take significantly different approaches to disclosure, resulting in unequal public access, increased administrative burden, and potential exposure of sensitive information.

In addition to concerns regarding privacy and proprietary information, expanded public posting requirements may create risks for individuals associated with controversial or highly visible areas of research. Publicly accessible information may increase the likelihood of online harassment, intimidation, doxxing, or targeting of researchers, biosafety personnel, institutional officials, and IBC members by individuals or groups opposed to particular research activities. These concerns are particularly relevant in an environment where personal information can be rapidly disseminated and amplified through social media and other online platforms.

NIH should ensure that transparency requirements promote public accountability while providing appropriate safeguards for individuals participating in the oversight and conduct of research. Clear national guidance regarding redaction, disclosure limitations, and protection of personally identifiable information would improve consistency across institutions while balancing transparency with legitimate privacy, security, and safety considerations.

5. Review Categories and Delegated Review

Comment

The draft policy establishes multiple review pathways, including NIH review, full IBC review, and delegated review; however, the boundaries between these categories are not always clear and may overlap. As written, institutions could reasonably reach different conclusions regarding which review pathway applies to the same activity. In addition, several review categories appear to encompass broad classes of biological materials or technologies without clearly explaining the risk-based criteria used to determine the appropriate level of oversight.

NIH should provide objective review-category criteria, decision trees, representative examples, and clear eligibility requirements that allow institutions to consistently determine when NIH review, full IBC review, or delegated review is required. The final policy should also clarify how overlapping categories should be reconciled and clearly explain the risk-based rationale for assigning research activities to different levels of review. Requirements should be distinguished from recommendations, and reviewer qualifications, documentation expectations, and escalation criteria should be clearly defined.

Rationale

Institutions must be able to classify research activities consistently and defensibly. The current framework creates uncertainty because individual research activities may fit within multiple review categories simultaneously, making it difficult to determine the appropriate review pathway. This ambiguity may result in inconsistent implementation across institutions, duplicate reviews, or assignment of comparable research activities to different levels of oversight.

In addition, several review categories appear to expand oversight based on the presence of certain biological materials, organisms, or forms of biological manipulation rather than on clearly articulated biological risk. This raises broader questions regarding whether oversight is intended to be risk-based or category-based. Without clearer distinctions and risk-based criteria, institutions may devote substantial review effort to activities with minimal biosafety implications while applying inconsistent standards to similar research.

A clearer framework that links review requirements to demonstrable biological risk would improve consistency, reduce administrative burden, facilitate appropriate use of delegated review, and allow IBC resources to remain focused on research activities requiring the greatest level of scientific and biosafety scrutiny.

6. Novel, Emerging, and Zoonotic Agents

Comment

The draft policy appears to require additional NIH involvement when organisms, agents, or biological materials lack established Risk Group classifications or containment recommendations. However, the process for obtaining federal determinations, the information required for submission, and expected review timelines are not clearly described.

NIH should establish a transparent process for evaluating novel, emerging, or previously uncharacterized biological agents, including submission requirements, review timelines, expedited pathways where appropriate, and expectations for institutional oversight while federal determinations are pending.

Rationale

Research involving emerging biological agents often occurs under circumstances where timely scientific evaluation is important. Without clearly defined review processes and timelines, institutions may experience uncertainty regarding research initiation, containment expectations, and compliance obligations. Transparent review pathways would improve predictability while ensuring appropriate oversight of emerging biological risks.

7. Incident Reporting

Comment

The draft policy expands institutional incident reporting requirements but does not sufficiently define key terms such as "incident," "compliance violation," "potential release," or "potential laboratory-acquired infection." The policy should provide clearer criteria regarding what events must be reported, when reports are required, and what information should be included.

NIH should establish risk-based reporting thresholds, reporting timelines, report-content requirements, and representative examples of reportable and non-reportable events. Requirements should focus on events that present meaningful biosafety concerns while minimizing duplicative reporting obligations.

Rationale

Incident reporting systems are most effective when reporting requirements are clear, consistent, and focused on events that provide meaningful opportunities for risk reduction and institutional learning. Broad or ambiguous reporting requirements may lead to inconsistent reporting practices, administrative burden, and uncertainty regarding compliance obligations. Greater clarity would improve the quality and usefulness of reported information while supporting national biosafety oversight objectives.

8. Workload, Resources, and Implementation

Comment

The draft policy would substantially increase institutional responsibilities related to protocol review, public disclosure, incident reporting, training, recordkeeping, information management, and oversight of activities not currently subject to review under the NIH Guidelines. The proposed implementation timeline may not provide sufficient time for institutions to revise governance structures, update electronic systems, develop procedures, train personnel, and review existing research activities.

NIH should provide a phased implementation schedule, grandfathering or transition provisions for currently approved research, model guidance documents, standardized training resources, and implementation tools that support consistent adoption across institutions.

Rationale

Successful implementation of a policy of this scope requires substantial institutional planning and resource allocation. Without adequate transition time and implementation support, institutions may face significant compliance challenges while attempting to maintain ongoing research operations. A phased implementation approach would promote higher-quality compliance, reduce operational disruption, and improve consistency across institutions while allowing NIH to address implementation questions that emerge during the transition period.

175. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Purpose and program identity
Policy reference Section I
The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.
Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation
Policy reference Section II
Coverage and decision rules
The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered. You may consider applying this only to NIH funded work.
Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.
Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement

or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.
Implementation period
The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.
Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. NIH implementation responsibilities and coordination
Policy reference Section III D
The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.
Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.
4. NIH review and containment determinations
Policy reference Section IV 1 with related petition provisions in Section III B
The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.
Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 3. IBC establishment functions and operations
Policy reference Section III B
Formal establishment and independent authority
The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.
Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language. The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.
As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent

biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program

administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

3. Continued utility of Risk Groups: 3. Risk assessment and specialized materials
Policy reference Sections V A through V E
The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.
Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.
Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): 1. Investigator responsibilities and voluntary reporting
Policy reference Section III C
The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.
Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.
Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The template for IBC meeting minutes is very extensive. Listing all of this information in the meeting minutes seems unnecessary as all of this information is already in the IBC protocol which IBC member already reviews and meeting minutes are captured at the time of review. The meeting minutes should stick to any controversial issues, the vote, etc. Committee members can always go back and review the protocol to review the information. Posting of the project details on a website also exposes the potential scooping of someone's work as well as potential security risks when all pathogens needs to be listed, etc. It is suggested that the template be consolidated to only require the vote and discussion and a small summary of the purpose of the study rather than an extensive explanation of what is occurring.

6. Other feedback relevant to this resource: 2. Institutional accountability and Biosafety Assurances
Policy reference Section III A
Accountability and minimum program support
The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.
Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions.
Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.
Assurance submission approval and renewal
A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.
Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.
Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.
Requests for consideration. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.
Public disclosure and record retention
The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.
Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.
Incident thresholds investigations and reporting
The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-

failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.
Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.
Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.
Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

1. IBC review pathways and clinical oversight
Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B
Category boundaries and continuing review
Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.
Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals. You may want to consider getting rid of the term de novo review to avoid confusion. Are annual reviews required and what is what required for an annual review – can this be accomplished through an inspection, etc.
Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.
Proposed designated member review procedure
Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

176. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Safety Professional

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Microbiology, Immunology, Pathology, infectious epidemiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent. In the draft Policy it appears that the policy is limited to only research involving "biomedical research, in laboratory settings, involving biohazards". If this is the care, the title of the policy and intent should be consistent with the directive or mission and the directive is a policy for biomedical research: "NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting animals, plants, agriculture, or the environment that in turn affect human health. This narrower scope is difficult to reconcile with the One Health approach and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

Broaden the scope to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of human, animal, plant, and environmental hazards while minimizing

administrative burden; or limit the scope explicitly to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Comment: Clarify the “known or potential risk to human health” threshold for Policy scope

NIH should clarify how the “known or potential risk to human health” threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a “potential risk to human health,” or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight. Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment: The definition of “genetic modification” expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving “known or potential risk to human health.” Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an

expansion of review, or both.

Suggested regulatory text (new exemption, or a note to Section IV-3):
Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3. IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. Adopt this structure in the final Policy or, if declined, explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequence. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of “known or potential risk to human health” applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. I recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.

Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

Human health cannot be considered independently of animal, agricultural, and environmental health. A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety policy should recognize these interconnected pathways.

Oversight should focus on the genetic modification and its credible consequences. The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

Existing animal-use oversight does not replace biosafety review. IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

Oversight should be coordinated across applicable authorities. Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

Institutional biosafety risk assessment: Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:
the nature and stability of the genomic modification;
whether the modification is heritable and the potential for transmission through breeding;
effects on animal health, phenotype, host range, susceptibility, or disease;
potential entry into breeding or food-production systems;
potential environmental release or interaction with non-research animal populations;
whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and
applicable federal, state, or other regulatory oversight.

Delegated review under Section IV-3: Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

Full IBC review under Section IV-2: Full IBC review should apply when the modification presents credible

higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

NIH or other federal review, as applicable: Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:
Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. I request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Policy Section II, Definitions

Comment:

The draft policy needs to define "biohazard" in the definitions section of the policy.

The draft policy uses the term “biological agent,” which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy’s scope extends well beyond select agents. We recommend replacing “biological agent” with “infectious microorganism or biological material,” consistent with Biosafety in Microbiological and Biomedical Laboratories (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

The draft policy uses the term “adventitious agents” in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with “primary cells that may be contaminated by adventitious agents”; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, “may be contaminated” could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3’s delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not deliberately introduced and is not part of the planned research; (2) replace “may be contaminated” in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

The phrase “potential risk to human health” is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. I recommend that NIH define “potential risk to human health” as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy’s scope or again make it a One Health approach and include animal, plant, environment disease that affects human health.

State explicitly that the Policy does not address non-biological hazards.

Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

The draft policy does not define “Transgenic animal.” We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal’s genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal’s genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

The proposed definition of “prion,” as misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals, is inconsistent with the Policy’s scope. It references neurodegenerative disease “in humans or animals,” whereas the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy’s scope, or address animal disease consistently across all agent types.

The proposed definition of “Toxins” should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka “sensitizers”).

Define “peptide” as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

Retain reassortment and non-transgenic methods within the “genetic modification” definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

Define “gene drive modified organisms” and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

Define “shedding” for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of “shedding, replicating, or integrating,” and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA’s Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes

shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate, and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

Use of "Universal Precautions" in clinical research settings. The draft states "However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection." We recommend revising the sentence to use current, risk-based infection-prevention terminology (Standard Precautions) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The Policy as drafted fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. NIH needs to clearly define the requirements, roles, and responsibilities of a BSO or a person who would take on the roles of a BSO as it relates to this proposed policy implementation and IBC oversight. As currently written, the policy ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

NIH and its partners need to define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.
While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at containment level BSL-2; therefore, leaving a large oversight gap. I recommend that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the aforementioned qualifiers.
The draft policy also adds additional regulatory burden on individuals taking on certain roles listed in the Functions section requiring substantial work including:
Periodic inspections
Incident response and investigation
24-hour notification
30-day reporting to NIH
Delegated review
Technical advice
Petitions to NIH
Enhanced reporting of IBC minutes

Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct

access to leadership/authority to support the identification and escalation of unresolved risks. I recommend a broad statement of qualifications rather than a mandatory degree or credential. Please consider the below proposed language:

The BSO or individual taking on roles similar, shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:
Education in the biological or physical sciences, with knowledge of microbiology and molecular biology; demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;
working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO, or designated role, has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the individual's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and SME and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered. It is recommended that each institution describe the following in its institutional plans/policies:

The BSO's, or individual taking on the role, reporting line has direct access to the Institutional Official and senior leadership;
access to all research spaces and records subject to the Policy;
authority to identify and escalate unresolved risks to the IBC and institutional leadership;
independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:
Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
Serving as a permanent voting IBC member and not restricted to certain work at the institution and, where permitted, as a designated or delegated reviewer;

Developing and delivering biosafety and biosecurity training;
Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
Assist with developing emergency response plans;
Coordinating with occupational health on medical surveillance and post-exposure response;
Advising on biosecurity, inventory, and material transfer;
Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.
Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to this financial burden, NIH should provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to each institutions leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. I recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must

therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. I encourage NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

3. Continued utility of Risk Groups: Comment: Risk Groups should not serve as a classification that drives laboratory oversight

I recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Rationale:
Risk Groups describe risk to healthy adults in the community. Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.

They reflect community exposure, not laboratory conditions. Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.

They have no baseline for novel constructs. Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.

They cover only human etiologic agents. Biohazards and biological material is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.

They are misinterpreted. Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

The terms are not interchangeable. Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.

The BMBL does not assign RGs. It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.

Comment: The role of "and any other applicable Federal, State, or local entities" is unclear. NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.

Comment: The scope of the petition requirement is unclear. As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.

Comment: Determinations should be published and reusable. Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. I ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): revamp the incident reporting template (see comments below)

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Comment: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While I support appropriate transparency regarding significant biosafety incidents and institutional responses, I strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, deidentified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment: Limit public content to information that supports transparency

NIH should not require public disclosure of:
Investigator's names
Grant numbers or internal project numbers
Sensitive animal research information
Select agent and toxin information
Proprietary materials and research outcomes
Identifying facility information
Other details that could compromise safety, security, including personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property, research information and national security over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements. It can be done and can be done securely.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual or quarterly Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when

redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4
Biosafety Level
Engineering Barrier Architecture
Incident Risk & Containment Impact
BSL-3 / ABSL-3
Primary containment (BSC/sealed cup) combined with directional negative airflow and 100% exhaust, and at times through HEPA filtration.
A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4
(Suit Lab)
Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.
A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure.
Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

Anchor 'Release' to Containment Boundaries: Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.

Calibrate by Biosafety Level: Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.

Define 'Exposures' and 'Medical Treatment': Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).

Eliminate Subjective Phrasing: Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, I propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

Release (Loss of Containment or Occupational exposure): Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

Incident: A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

6. Other feedback relevant to this resource: Comment: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment: Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research

Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

177. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Clarify which research activities fall under the policy and ensure that oversight requirements are proportionate to actual biosafety risks, particularly for routine, low-risk research.

178. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Ensure that Institutional Biosafety Committees (IBCs) and biosafety professionals have appropriate authority and institutional support to fulfill expanded responsibilities.

179. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Balance public transparency with protection of sensitive research information, individual privacy, and a strong safety culture that encourages reporting of incidents and near misses. HIPPAA rules and regulations come into play when we provide required information within the DRAFT we are commenting on

180. James Klenner MSc, MPH, MPA, RBP, CBSP

I am responding: On behalf of myself

Name: James Klenner MSc, MPH, MPA, RBP, CBSP

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Admin for IACUC, IBC, and Biosafety Officer

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: While oversight will cover all laboratory biohazards (wild-type pathogens, toxins, prions, etc.), untreated cells, tissues. fluids, and blood of human origin are not specifically addressed and may lead to confusion with the OSHA Bloodborne Pathogen Standard and DOT shipping requirements. We already oversee use of these materials on our campus but I can foresee the argument that, while not mentioned in the new NIH Biosafety Policy, they may argue the research is exempt from oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

181. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Recommend a minimum 24-month phased implementation period, accompanied by clear guidance, standardized tools, training, and appropriate resources. The proposed implementation is setting everyone up for failure.

182. TERRIE RIFE

I am responding: On behalf of myself

Name: TERRIE RIFE

Name of Organization: James Madison University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Molecular Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: It is clear to me that plants must fit into an oversight policy. We as humans eat them and do not want to eat plants that have been modified without the appropriate checks being done to know that they are safe. Thus, I don't completely understand why we are taking plants out of the policy without having another policy in place to oversee them.

In general the more clear that the definitions of what should be included in this policy are the better. I like that it is a bit more broad in scope but people should be allowed time to implement these policies and have them approved. Things like writing an assurance and taking the time to change into this new policy will take time and I don't want to see work of any individual faculty member slowed by administrative processes that need to happen for approval.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I am worried that you are not making a policy for all institutions. I see middle size institutions as likely being highly effected as they do not have as many resources as do larger institutions but likely have a variety of research happening so things like requiring a centralized Environmental Health and Safety Office may not be scalable at these institutes and able to accommodate all of the additional researchers and their students. They will have just enough resources to make things feel problematic but not enough to have easy access to resources to change their general policies. Smaller institutions will likely struggle too to implement the new systems although will likely have problems as well without the resources and personal to properly implement all of the layers of things that must happen in order for the researchers to meet the guidelines.

To do many of the things this policy asks for requires a larger infrastructure and probably a few more people. Where do the funds and money come to do this at smaller institutions that don't have excessive funds as this NIH policy expands to include more researchers.

Electronic systems for collecting data will need to be expanded and many changes will need to be made so time and resources for accomplishing this is a problem that needs some addressing.

Committee membership will need to change. None of this is bad, but will require time and resources. Giving smaller schools a bit more time to implement these changes would be helpful.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I am a bit worried about making incident reports public. I think its okay to ask for numbers of incident reports from a given institution and the general nature of those incidents and put that into the public scope but we should be careful about not pushing so much information out there that the public becomes generally more worried about what we are doing because information is more freely available. There is a certain type of incident that yes the public may need to know the nature of it in order to remain safe but most small spills in the lab are just things that happen. I think you will get less reporting of them because you are asking for them to be public rather than more reporting and that is not good. The incidents should be reported so that if there is a problem it can be addressed.

6. Other feedback relevant to this resource: Generally make sure that appropriate amount of time is given for this. Having people available to answer questions as Universities begin to implement these policies.

183. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Life sciences research in higher education.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Define the boundary of the policy:
The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define "biohazard." The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define "biohazard" and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology:
The definition of "biological agent" is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage:
The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk:

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses "prions and other self-aggregating proteins" in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability:
"Biomedical research" should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals:
NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Create a clear precedence rule:
Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight:
Delegated review is a welcome modernization, but requiring every approval to be reported "in full" at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee's role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities:
Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances:
Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during

environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable:
NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Continued utility of Risk Groups: Retain Risk Groups as a starting point
Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change:
The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment:
A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Align accountability with authority:
The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies:
The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately:

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements:
A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting:
Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules:
If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types:
The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Preserve the clearer federal reporting thresholds:
CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories:
The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." The policy should clarify whether precautionary post exposure prophylactic treatment is considered "agent-specific treatment". It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish

administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview:
NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting:
The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

6. Other feedback relevant to this resource: Provide a minimum 24-month phased implementation period:
The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates:
NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources:
Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance:
The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures,

workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models:
The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Uploaded File: CSHEMA-NIH-Comments-1.pdf

Description: To Whom It May Concern: I am submitting this comment in response to the National Institutes of Health (NIH) effort to modernize and strengthen the oversight of biosafety. I support the comment submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA) regarding this effort. CSHEMA's comment appropriately reflects the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs. As an individual, a biosafety officer working in higher education, my work would be directly impacted by a new NIH policy on biosafety and I support the recommendations outlined by CSHEMA. Given the lack of comprehensive definitions, multiple contradictions, and limited clarity in the proposed policy, it is challenging for institutions to have a full grasp of the level of impact this new doctrine will have. I humbly request that the NIH consider offering second draft for stakeholder review and comment before issuing the final policy. Thank you for the opportunity to comment.

Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards

Response to NOT-OD-26-112

October 12, 2026

Submitted Electronically

The Campus Safety, Health, and Environmental Management Association (CSHEMA) is the premier association for environmental health and safety leadership in higher education. CSHEMA represents institutions that range from large research-intensive universities with mature biosafety programs to smaller colleges that may have limited or no dedicated biosafety staff. Our members include biosafety professionals, environmental health and safety practitioners, and institutional leaders responsible for implementing biosafety requirements across diverse research and teaching environments.

CSHEMA appreciates NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions. **Due to such uncertainty in the final requirements, CSHEMA encourages NIH to provide an opportunity for public review and comment on the next draft before it is finalized.**

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." The policy should clarify whether precautionary post exposure prophylactic treatment is considered "agent-specific treatment". It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

6. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

CSHEMA recommends that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

Conclusion

CSHEMA supports NIH's goal of modernizing biosafety oversight and appreciates the draft's movement toward broader risk awareness, clearer incident thresholds, delegated review, and national safety learning. For the policy to succeed, however, modernization must strengthen the institutional systems that perform biosafety work rather than simply expand their obligations.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified

local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

CSHEMA respectfully requests that NIH revise the draft consistent with these recommendations, release complete implementation materials for public review, pilot key templates and processes, and provide a minimum 24-month phased implementation period. CSHEMA welcomes continued engagement and would be pleased to assist NIH in testing implementation resources or gathering additional institutional perspectives.

Sincerely,



Robin Izzo
President
Campus Safety, Health, and Environmental Management Association

184. Stephen Miller

I am responding: On behalf of myself

Name: Stephen Miller

Name of Organization: University of Maryland Baltimore County

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Developmental Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The new policy exempts plant research from biohazard review. I'd like a clarification about this part of the policy. Is algal research also exempt, and what about research on phytoplankton/diatoms and other photosynthetic organisms that are not infectious towards humans or other animals?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

185. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

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The unification of oversight for all research involving biohazards, whether or not such research involves recombinant or synthetic nucleic acid technology, is a positive change and one that supports a more comprehensive and cohesive institutional biosafety program. The addition of a Delegated Review mechanism is another positive change, which reduces the burden on IBCs, while providing institutions with the flexibility to define the Delegated Review process in a way that ensures appropriate oversight of lower-risk activities at individual institutions. We support these notable policy improvements.

While many aspects of the draft Policy represent improvements, there are several changes that are likely to have significant negative consequences, as well as points that would benefit from clarification. We respectfully submit the comments below for consideration to further improve the Policy.

1. New incident reporting requirements have an expanded scope of what counts as an incident in addition to the requirement to post all incident reports on a public website.

    a. **Impact:** These changes are expected to have a significant negative impact. The trust that biosafety programs have built up over the years in supporting researchers and encouraging people to report accidents will be eroded by fear of negative ramifications and/or retaliatory action. Even if reporting is anonymized and only a PI or supervisor name is included in the published report, there is a perceived risk of that information being used against the person, lab, and/or institution. People will be less likely to report accidents, which increases the risks associated with untreated injuries or exposures to hazardous materials.

    b. **Recommendation 1**: Individual incident reports should not be publicly posted. Reporting should be to NIH, where data on incidents can be aggregated and trends analyzed and/or reported in a way that removes institutional affiliation to further anonymize individuals involved in an incident. That allows for analysis of the data and identification of trends, which would be a valuable resource to the community, while avoiding negative consequences on the individual, lab, or institution, which would, in turn, undermine the value of the incident reporting process.

    c. **Recommendation 2**: If institutions must be required to publicly post incident information, allow an aggregated annual report. Such an approach could be modeled after OSHA's Form 300A (Summary of Work-Related Injuries and Illnesses). We would strongly recommend this approach for incidents defined by this Policy, which would not be reported to NIH but would be reported to the IBC.

2. The draft Policy states that IBC approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required. It further lists failure to maintain IBC approval as a reportable incident.

    a. **Impact:** The expected impacts of these changes are a significantly increased administrative burden and unintentional non-compliance. In the absence of a specified term limit, many institutions adopted internal policies that require IBC approval to be renewed within a 5-year period, which also coincides with the length of many grants supporting the approved research activities. Switching to a shorter 3-year renewal cycle presents a significant increase in committee workload. Additionally, well-intentioned PIs may face unexpected emergencies, or their registration renewal may come at a time when they are burdened with high workloads from teaching and/or other institutional responsibilities. Because there is no mechanism described in the draft Policy for allowing extensions to PIs facing extenuating circumstances, failure to renew an IBC registration on time would result in a reportable incident of non-compliance.

    b. **Recommendation 1:** Keep a defined term limit on IBC approval but increase the term of IBC approval to 5 years.

    c. **Recommendation 2:** Empower IBCs to exercise judgement and flexibility in granting reasonable, one-time extensions to PIs facing extenuating circumstances and/or moving a registration renewal to a different time of year so as not to conflict with other high-workload periods.

3. The draft Policy states that research with primary cells that may be contaminated by adventitious agents requires IBC review and approval under Section IV-2. We interpret this new scope to mean that any primary human cell line, tissue, or clinical specimen with an unknown status (has not been tested for bloodborne pathogens or other infectious agents) will have to go to the IBC for approval, whereas none of this material required IBC review previously. Instead, this material fell under the OSHA Bloodborne Pathogens Standard, which requires institutions to establish oversight mechanisms that have worked for many decades.

    a. **Impact**: This change is expected to have a significant negative impact. The increased burden on most IBCs will be enormous, with no apparent benefit, since the existing mechanisms to comply with the OSHA Bloodborne Pathogens Standard must still be maintained. This is an unnecessary duplication of oversight, and the increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation**: Allow this type of material to be approved via the new Delegated Review process described in Section IV-3 rather than requiring IBC

review. That would allow institutions flexibility to integrate existing biosafety oversight mechanisms into the Delegated Review process defined by the new Policy.

4. The draft Policy states that research involving genetically modified cells, viruses, or organisms, other than plants requires IBC approval and approval under Section IV-2. Previously, a large portion of genetically modified cell lines were considered exempt under Section III-F-8, Appendix C-I. For many IBCs, that type of material made up the majority of genetically modified material, and because it was considered exempt and did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely and in accordance with the OSHA Bloodborne Pathogens Standard. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8, Appendix C-I now falls under Section IV-2 and requires full committee review.

    a. **Impact**: This change is expected to have a <u>significant negative impact</u>. This will create an enormous new burden on IBCs, with no apparent benefit because the main risk associated with material that fell under Section III-F-8, Appendix C-I was the risk of adventitious agents or bloodborne pathogens, as mentioned in point 3 above. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation**: Retain the Section III-F-8, Appendix C-I exemption, or allow materials that would have fallen under Section III-F-8, Appendix C-I to be approved via the Delegated Review process described in Section IV-3.

5. The draft Policy's definition of a genetic modification includes introduction into cells, organisms, or viruses of stable alterations into the genome by passaging. It is not clear what passaging activity falls within the Policy scope. Simply culturing an organism in vitro will lead to accumulation of undefined genetic alterations and could be considered passaging. Cultures that are maintained in a lab are also considered to be passaged through the process of sub-culturing to create multiple stocks from an original sample. Further, most of the time, growing an organism in vitro or in a model system selects for mutations that optimize growth in a lab environment, not in a human host, and these lab-adapted strains typically lose virulence or pathogenicity. The Influenza A/Puerto Rico/8/1934 (H1N1) strain (often called PR8 influenza) is a classic, mouse-adapted laboratory strain of the influenza A virus isolated from a human patient in Puerto Rico in 1934. It is an example of a strain that is a lower risk option for studying influenza. These examples of passaging generally have not required IBC review. In the draft Policy, all of these activities would require IBC review and approval under Section IV-2 (see also point 4 above).

a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because most passaging does not increase the risk of the agent or associated research activities. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

b. **Recommendation**: We recommend refining the scope of the definition of genetic modifications by defining passaging as the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile. Examples of passaging activities that should be included in Section IV-2 include passaging with the intent or likelihood for an agent to acquire a new virulence trait or antibiotic resistance or to adapt a pathogen to a new host species and/or tissue tropism.

6. In the draft Policy, the definition of genetic modification that falls within the scope of the policy now includes modification via chemical or radiological means. Further, the draft Policy requires the IBC to review all genetically modified cells under Section IV-2 (see also point 4 above). The main risk associated with use of chemical or radiological agents to create mutations is in the handling of the chemical or radiological material, not necessarily in handling the cells once the mutagen has been removed. There are separate regulations that apply to chemical and radiological hazards. The use of chemical and radiological hazards is best handled by the respective safety experts who are familiar with the appropriate regulations and safety requirements, not the IBC. Assessment of the risks of these mutagens are outside of the scope of an IBC, since IBC members typically have little to no expertise on chemical or radiological hazards.

    a. **Impact**: This is a vast expansion of scope that will duplicate oversight and increase burden on IBCs, without a clear benefit. Further, the IBCs typically lack appropriate expertise for evaluating the risks associated with these mutagens. The increased burden on IBCs will detract attention from higher-risk matters, which do fall within the expertise of the committee.

    b. **Recommendation**: Remove chemical and radiological means from the definition of genetic modifications that fall within the scope of the policy and defer oversight to existing regulations that apply to the use of chemical and radiological hazards. Alternatively, refine the scope to apply to experiments in which the mutagenic agent is combined with the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile, as recommended for passaging in point 5 above.

7. The draft policy states that research with genetically modified RG1 biological agents requires Delegated Review under Section IV-3. Previously, most standard cloning and/or

protein expression with *E. coli* and other model host-vector systems were considered exempt under Section III-F-8, and it did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely with proper waste disposal procedures. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8 now requires Delegated Review.

a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. The increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

b. **Recommendation 1**: We strongly recommend retaining existing III-F-1 through III-F-8 exemptions.

c. **Recommendation 2**: Furthermore, and supported by decades of safe research experience, we also recommend expanding the exemptions to include other low-risk cloning and protein expression research in model organisms such as *E. coli* BL21 strains, *C. elegans*, and *Drosophila*.

8. The draft Policy states that research conducted with transgenic organisms at BSL-1/ABSL-1" requires Delegated Review. Previously, almost all breeding or purchasing of transgenic rodents was exempt under Section III-F-8, Appendix C-VII and was not typically registered with an IBC at all. Instead, oversight of those transgenic rodents typically has been handled through federally mandated Institutional Animal Care and Use Committees (IACUCs) that have biosafety professionals as members who conduct risk assessments and suggest risk mitigation measures as part of that review process. Many IBCs do not even have a mechanism for tracking this information. Additionally, many researchers using transgenic mice are not using any other sort of biological material; the research is often focused on behavioral studies or pre-clinical studies that fall outside the scope of an IBC. A very large proportion of transgenic animal work is done with transgenic rodents and zebrafish, and almost all of that work poses no new risk compared to the unmodified rodents and zebrafish.

    a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. Again, the increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

    b. **Recommendation 1**: We strongly recommend retaining the III-F-8, Appendix C-VII exemption and allow existing oversight of these low-risk animals to continue via the IACUC.

c. **Recommendation 2**: As mentioned in point 7 above, we also recommend expanding the exemptions to include other low-risk transgenic model organisms such as zebrafish, *C. elegans* and *Drosophila*.

9. The draft Policy defines biological agents that fall within the scope as bacteria, viruses, fungi, or parasites that cause human disease. This definition seems to contradict the draft Policy's requirement for Delegated Review of research with genetically modified RG1 biological agents (see point 7 above). Risk Group 1 agents are not associated with disease in healthy adult humans. Some agents may be considered opportunistic pathogens, but there is currently no list of RG1 organisms that are considered opportunistic pathogens.

    a. **Recommendation 1:** NIH should clarify the nature of biological agents that fall within the scope of the Policy. We recommend that the Policy scope is limited to pathogenic biological agents that cause disease in humans, including opportunistic pathogens but excluding non-pathogenic agents.

    b. **Recommendation 2**: As there is no list of RG1 agents, and the list of RG2 agents is incomplete, we further recommend empowering the IBCs, Biosafety programs, and PIs to make the determination of RG1 and RG2 for biological agents that are not currently listed in Appendix B of the NIH Guidelines or the BMBL using the risk assessment guidance provided therein.

10. The draft Policy's definition of a genetic modification includes introduction of materials that can be transcribed or translated. This would include materials such as purified or synthetic miRNAs, snRNAs, shRNAs, and mRNAs, which are transient in nature and may lead to changes in gene expression but do not replicate and do not modify or integrate into the genome. Work with such materials was previously exempted under III-F-1 but would now fall under Section IV-2 and require IBC review and approval.

    a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create a significant new burden on IBCs, with no apparent benefit given that no genetic modifications are made with these materials. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation:** We recommend retaining the III-F-1 exemption and removing these materials from the scope of the Policy.

11. The scope of the draft Policy includes prions and self-aggregating proteins, and research activities involving these materials would require IBC review and approval. We support the draft Policy as it pertains to prions, but request refinement of the oversight pertaining to self-aggregating proteins. IBC oversight should not extend automatically to every protein capable of self-aggregation. Protein aggregation is common in biology and,

by itself, does not establish an infectious or exposure hazard. Oversight should instead focus on proteins or protein assemblies for which there is credible evidence that an aggregated conformer can act as a persistent, self-propagating seed; induce conformational conversion of the corresponding native protein; spread between cells or tissues; and transmit pathology following experimental exposure or inoculation. We recommend the following risk-assessment approach, which is consistent with the BMBL principle that containment decisions should be protocol-driven rather than based only on an agent's name.

a. **Recommendation 1:** Classical mammalian prions and prion-containing tissues should remain categorically within IBC purview because of their established infectivity, potential for serious disease, environmental persistence, and resistance to conventional inactivation procedures.

b. **Recommendation 2:** Seed-competent aggregates of α-synuclein, including preformed fibrils, amplified seeds, and α-synuclein-containing material derived from affected human or animal tissue, should also be subject to IBC review because α-synuclein assemblies have demonstrated prion-like templating, cellular and anatomical propagation, and experimental transmissibility in animal models. Inclusion under IBC oversight should not be understood to mean that α-synuclein is known to be naturally communicable between people or that it presents the same level of hazard as a classical prion.

c. **Recommendation 3:** Other self-aggregating proteins should be evaluated individually rather than be included in Section IV-2 of the draft Policy solely because they form oligomers, fibrils, or amyloid. Relevant considerations should include evidence of experimentally transmissible pathology, persistence of seeding activity, resistance to standard decontamination, source and concentration of the material, route and scale of exposure, use of human- or animal-derived pathological tissue, and procedures involving inoculation, sharps, aerosols, or other opportunities for occupational exposure. Routine work with non-seed-competent monomeric proteins or aggregates lacking evidence of biological propagation would not ordinarily require specialized biosafety review beyond the requirements otherwise applicable to the experimental system, and we recommend that the Delegated Review mechanism described in Section IV-3 be applied to such work.

12. The scope of the draft Policy includes toxins listed as Select Agents, and research activities involving these materials would require IBC review and approval under Section IV-2, while research with biological toxin proteins not on the Select Agent list may be approved by Delegated Review under Section IV-3. We support this overall approach; however, we request refinement of the Policy with the following recommendations.

a. **Recommendation 1:** Allow research activities using exempt amounts of Select Agent toxins to be approved by Delegated Review. Most institutions have already developed effective internal biosafety oversight mechanisms for handling these exempted materials. Integrating those internal oversight mechanisms into the Delegated Review process would allow IBCs to focus on the higher-risk Select Agent work.

b. **Recommendation 2:** Either publish a list of biological toxins that fall within the scope of the Policy or use a threshold toxicity value as a risk-based factor for determining whether a biological toxin requires oversight by the Policy. We further recommend that biological toxins that have an LD_{50} greater than 1000 µg/kg be exempt from this Policy.

13. The scope of the draft Policy includes cells, viruses, or organisms, other than plants, that have been genetically modified. It is assumed that animals are included as organisms, but it is not clear what is considered an animal under this Policy.

    a. **Recommendation:** Use a definition of animal that is consistent with the Guide for the Care and Use of Laboratory Animals, which has been adopted by the NIH Office of Laboratory Animal Welfare, and which defines animals as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

14. The draft Policy indicates that the effective date will be 6 months from publication of final Policy, and that applicability includes ongoing work. It is unclear how ongoing work will be impacted by the new review and approval requirements. Work that was not subject to IBC oversight according to the NIH Guidelines may have been approved via voluntary institutional biosafety oversight mechanisms.

    a. **Impact:** Work that was approved by a Biosafety Officer (or other institutional biosafety oversight) and now requires a higher level of review by the IBC would need to cease until IBC approval is obtained. This would have a significant negative impact on a large number of projects that are suddenly subject to new oversight, thereby wasting grant money and setting back important research projects.

    b. **Recommendation:** Require activities that have not received approval by a Biosafety Officer or other institutional biosafety oversight mechanism to be reviewed and approved according to the final Policy within 6 months of the publication of the final Policy. For activities that have received approval by a Biosafety Officer or other institutional biosafety oversight mechanism, allow the existing approval to remain in place until such time as de novo registration is

required (see point 2 regarding our recommendation to allow 5-year term limits for IBC registration approvals).

186. Massachusetts Institute of Technology

I am responding: On behalf of an organization

Name:

Name of Organization: Massachusetts Institute of Technology

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: MIT-letter-to-NIH-OSP_FINAL.pdf

Description: feedback on the proposed policy from the MIT Institutional Biosafety Committee

Massachusetts Institute of Technology

Committee on the Assessment of Biohazards and Embryonic Stem Cell Research Oversight

Environment, Health & Safety Office
Building N52-496

77 Massachusetts Avenue
Cambridge, Massachusetts
02139–4307

Phone 617–253-1740
cabescro.mit.edu

Date: October 15, 2026

To: National Institutes of Health, Office of Science Policy

RE: The Draft NIH Biosafety Policy for Research Involving Biohazards

The Committee on Assessment of Biohazards and Embryonic Stem Cell Research Oversight (CAB/ESCRO) is the Institutional Biosafety Committee (IBC) at the Massachusetts Institute of Technology and was formed in January of 1975 to ensure the safe and responsible conduct of biological research at MIT. The CAB/ESCRO appreciates the opportunity to provide feedback on the Draft NIH Biosafety Policy for Research Involving Biohazards that will replace the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

The unification of oversight for all research involving biohazards, whether or not such research involves recombinant or synthetic nucleic acid technology, is a positive change and one that supports a more comprehensive and cohesive institutional biosafety program. The addition of a Delegated Review mechanism is another positive change, which reduces the burden on IBCs, while providing institutions with the flexibility to define the Delegated Review process in a way that ensures appropriate oversight of lower-risk activities at individual institutions. We support these notable policy improvements.

While many aspects of the draft Policy represent improvements, there are several changes that are likely to have significant negative consequences, as well as points that would benefit from clarification. We respectfully submit the comments below for consideration to further improve the Policy.

1. New incident reporting requirements have an expanded scope of what counts as an incident in addition to the requirement to post all incident reports on a public website.

    a. **Impact:** These changes are expected to have a significant negative impact. The trust that biosafety programs have built up over the years in supporting researchers and encouraging people to report accidents will be eroded by fear of negative ramifications and/or retaliatory action. Even if reporting is anonymized and only a PI or supervisor name is included in the published report, there is a perceived risk of that information being used against the person, lab, and/or

institution. People will be less likely to report accidents, which increases the risks associated with untreated injuries or exposures to hazardous materials.

b. **Recommendation 1**: Individual incident reports should not be publicly posted. Reporting should be to NIH, where data on incidents can be aggregated and trends analyzed and/or reported in a way that removes institutional affiliation to further anonymize individuals involved in an incident. That allows for analysis of the data and identification of trends, which would be a valuable resource to the community, while avoiding negative consequences on the individual, lab, or institution, which would, in turn, undermine the value of the incident reporting process.

c. **Recommendation 2**: If institutions must be required to publicly post incident information, allow an aggregated annual report. Such an approach could be modeled after OSHA's Form 300A (Summary of Work-Related Injuries and Illnesses). We would strongly recommend this approach for incidents defined by this Policy, which would not be reported to NIH but would be reported to the IBC.

2. The draft Policy states that IBC approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required. It further lists failure to maintain IBC approval as a reportable incident.

   a. **Impact:** The expected impacts of these changes are a <u>significantly increased administrative burden and unintentional non-compliance.</u> In the absence of a specified term limit, many institutions adopted internal policies that require IBC approval to be renewed within a 5-year period, which also coincides with the length of many grants supporting the approved research activities. Switching to a shorter 3-year renewal cycle presents a significant increase in committee workload. Additionally, well-intentioned PIs may face unexpected emergencies, or their registration renewal may come at a time when they are burdened with high workloads from teaching and/or other institutional responsibilities. Because there is no mechanism described in the draft Policy for allowing extensions to PIs facing extenuating circumstances, failure to renew an IBC registration on time would result in a reportable incident of non-compliance.

   b. **Recommendation 1:** Keep a defined term limit on IBC approval but increase the term of IBC approval to 5 years.

   c. **Recommendation 2:** Empower IBCs to exercise judgement and flexibility in granting reasonable, one-time extensions to PIs facing extenuating circumstances and/or moving a registration renewal to a different time of year so as not to conflict with other high-workload periods.

3. The draft Policy states that research with primary cells that may be contaminated by adventitious agents requires IBC review and approval under Section IV-2. We interpret this new scope to mean that any primary human cell line, tissue, or clinical specimen with an unknown status (has not been tested for bloodborne pathogens or other infectious agents) will have to go to the IBC for approval, whereas none of this material required IBC review previously. Instead, this material fell under the OSHA Bloodborne Pathogens Standard, which requires institutions to establish oversight mechanisms that have worked for many decades.

    a. **Impact**: This change is expected to have a significant negative impact. The increased burden on most IBCs will be enormous, with no apparent benefit, since the existing mechanisms to comply with the OSHA Bloodborne Pathogens Standard must still be maintained. This is an unnecessary duplication of oversight, and the increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation**: Allow this type of material to be approved via the new Delegated Review process described in Section IV-3 rather than requiring IBC review. That would allow institutions flexibility to integrate existing biosafety oversight mechanisms into the Delegated Review process defined by the new Policy.

4. The draft Policy states that research involving genetically modified cells, viruses, or organisms, other than plants requires IBC approval and approval under Section IV-2. Previously, a large portion of genetically modified cell lines were considered exempt under Section III-F-8, Appendix C-I. For many IBCs, that type of material made up the majority of genetically modified material, and because it was considered exempt and did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely and in accordance with the OSHA Bloodborne Pathogens Standard. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8, Appendix C-I now falls under Section IV-2 and requires full committee review.

    a. **Impact**: This change is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because the main risk associated with material that fell under Section III-F-8, Appendix C-I was the risk of adventitious agents or bloodborne pathogens, as mentioned in point 3 above. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

b. **Recommendation**: Retain the Section III-F-8, Appendix C-I exemption, or allow materials that would have fallen under Section III-F-8, Appendix C-I to be approved via the Delegated Review process described in Section IV-3.

5. The draft Policy's definition of a genetic modification includes introduction into cells, organisms, or viruses of stable alterations into the genome by passaging. It is not clear what passaging activity falls within the Policy scope. Simply culturing an organism in vitro will lead to accumulation of undefined genetic alterations and could be considered passaging. Cultures that are maintained in a lab are also considered to be passaged through the process of sub-culturing to create multiple stocks from an original sample. Further, most of the time, growing an organism in vitro or in a model system selects for mutations that optimize growth in a lab environment, not in a human host, and these lab-adapted strains typically lose virulence or pathogenicity. The Influenza A/Puerto Rico/8/1934 (H1N1) strain (often called PR8 influenza) is a classic, mouse-adapted laboratory strain of the influenza A virus isolated from a human patient in Puerto Rico in 1934. It is an example of a strain that is a lower risk option for studying influenza. These examples of passaging generally have not required IBC review. In the draft Policy, all of these activities would require IBC review and approval under Section IV-2 (see also point 4 above).

    a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because most passaging does not increase the risk of the agent or associated research activities. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation**: We recommend refining the scope of the definition of genetic modifications by defining passaging as the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile. Examples of passaging activities that should be included in Section IV-2 include passaging with the intent or likelihood for an agent to acquire a new virulence trait or antibiotic resistance or to adapt a pathogen to a new host species and/or tissue tropism.

6. In the draft Policy, the definition of genetic modification that falls within the scope of the policy now includes modification via chemical or radiological means. Further, the draft Policy requires the IBC to review all genetically modified cells under Section IV-2 (see also point 4 above). The main risk associated with use of chemical or radiological agents to create mutations is in the handling of the chemical or radiological material, not necessarily in handling the cells once the mutagen has been removed. There are separate regulations that apply to chemical and radiological hazards. The use of chemical and radiological hazards is best handled by the respective safety experts who are familiar with the appropriate regulations and safety requirements, not the IBC.

Assessment of the risks of these mutagens are outside of the scope of an IBC, since IBC members typically have little to no expertise on chemical or radiological hazards.

a. **Impact**: This is a vast expansion of scope that will duplicate oversight and increase burden on IBCs, without a clear benefit. Further, the IBCs typically lack appropriate expertise for evaluating the risks associated with these mutagens. The increased burden on IBCs will detract attention from higher-risk matters, which do fall within the expertise of the committee.

b. **Recommendation**: Remove chemical and radiological means from the definition of genetic modifications that fall within the scope of the policy and defer oversight to existing regulations that apply to the use of chemical and radiological hazards. Alternatively, refine the scope to apply to experiments in which the mutagenic agent is combined with the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile, as recommended for passaging in point 5 above.

7. The draft policy states that research with genetically modified RG1 biological agents requires Delegated Review under Section IV-3. Previously, most standard cloning and/or protein expression with *E. coli* and other model host-vector systems were considered exempt under Section III-F-8, and it did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely with proper waste disposal procedures. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8 now requires Delegated Review.

   a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. The increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

   b. **Recommendation 1**: We strongly recommend retaining existing III-F-1 through III-F-8 exemptions.

   c. **Recommendation 2**: Furthermore, and supported by decades of safe research experience, we also recommend expanding the exemptions to include other low-risk cloning and protein expression research in model organisms such as *E. coli* BL21 strains, *C. elegans*, and *Drosophila*.

8. The draft Policy states that research conducted with transgenic organisms at BSL-1/ABSL-1" requires Delegated Review. Previously, almost all breeding or purchasing of transgenic

rodents was exempt under Section III-F-8, Appendix C-VII and was not typically registered with an IBC at all. Instead, oversight of those transgenic rodents typically has been handled through federally mandated Institutional Animal Care and Use Committees (IACUCs) that have biosafety professionals as members who conduct risk assessments and suggest risk mitigation measures as part of that review process. Many IBCs do not even have a mechanism for tracking this information. Additionally, many researchers using transgenic mice are not using any other sort of biological material; the research is often focused on behavioral studies or pre-clinical studies that fall outside the scope of an IBC. A very large proportion of transgenic animal work is done with transgenic rodents and zebrafish, and almost all of that work poses no new risk compared to the unmodified rodents and zebrafish.

a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. Again, the increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

b. **Recommendation 1**: We strongly recommend retaining the III-F-8, Appendix C-VII exemption and allow existing oversight of these low-risk animals to continue via the IACUC.

c. **Recommendation 2**: As mentioned in point 7 above, we also recommend expanding the exemptions to include other low-risk transgenic model organisms such as zebrafish, *C. elegans* and *Drosophila*.

9. The draft Policy defines biological agents that fall within the scope as bacteria, viruses, fungi, or parasites that cause human disease. This definition seems to contradict the draft Policy's requirement for Delegated Review of research with genetically modified RG1 biological agents (see point 7 above). Risk Group 1 agents are <u>not</u> associated with disease in healthy adult humans. Some agents may be considered opportunistic pathogens, but there is currently no list of RG1 organisms that are considered opportunistic pathogens.

    a. **Recommendation 1:** NIH should clarify the nature of biological agents that fall within the scope of the Policy. We recommend that the Policy scope is limited to pathogenic biological agents that cause disease in humans, including opportunistic pathogens but <u>excluding</u> non-pathogenic agents.

    b. **Recommendation 2**: As there is no list of RG1 agents, and the list of RG2 agents is incomplete, we further recommend empowering the IBCs, Biosafety programs, and PIs to make the determination of RG1 and RG2 for biological agents that are not currently listed in Appendix B of the NIH Guidelines or the BMBL using the risk assessment guidance provided therein.

10. The draft Policy's definition of a genetic modification includes introduction of materials that can be transcribed or translated. This would include materials such as purified or synthetic miRNAs, snRNAs, shRNAs, and mRNAs, which are transient in nature and may lead to changes in gene expression but do not replicate and do not modify or integrate into the genome. Work with such materials was previously exempted under III-F-1 but would now fall under Section IV-2 and require IBC review and approval.

    a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create a significant new burden on IBCs, with no apparent benefit given that no genetic modifications are made with these materials. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation:** We recommend retaining the III-F-1 exemption and removing these materials from the scope of the Policy.

11. The scope of the draft Policy includes prions and self-aggregating proteins, and research activities involving these materials would require IBC review and approval. We support the draft Policy as it pertains to prions, but request refinement of the oversight pertaining to self-aggregating proteins. IBC oversight should not extend automatically to every protein capable of self-aggregation. Protein aggregation is common in biology and, by itself, does not establish an infectious or exposure hazard. Oversight should instead focus on proteins or protein assemblies for which there is credible evidence that an aggregated conformer can act as a persistent, self-propagating seed; induce conformational conversion of the corresponding native protein; spread between cells or tissues; and transmit pathology following experimental exposure or inoculation. We recommend the following risk-assessment approach, which is consistent with the BMBL principle that containment decisions should be protocol-driven rather than based only on an agent's name.

    a. **Recommendation 1:** Classical mammalian prions and prion-containing tissues should remain categorically within IBC purview because of their established infectivity, potential for serious disease, environmental persistence, and resistance to conventional inactivation procedures.

    b. **Recommendation 2:** Seed-competent aggregates of α-synuclein, including preformed fibrils, amplified seeds, and α-synuclein-containing material derived from affected human or animal tissue, should also be subject to IBC review because α-synuclein assemblies have demonstrated prion-like templating, cellular and anatomical propagation, and experimental transmissibility in animal models. Inclusion under IBC oversight should not be understood to mean that α-synuclein is known to be naturally communicable between people or that it presents the same level of hazard as a classical prion.

c. **Recommendation 3:** Other self-aggregating proteins should be evaluated individually rather than be included in Section IV-2 of the draft Policy solely because they form oligomers, fibrils, or amyloid. Relevant considerations should include evidence of experimentally transmissible pathology, persistence of seeding activity, resistance to standard decontamination, source and concentration of the material, route and scale of exposure, use of human- or animal-derived pathological tissue, and procedures involving inoculation, sharps, aerosols, or other opportunities for occupational exposure. Routine work with non-seed-competent monomeric proteins or aggregates lacking evidence of biological propagation would not ordinarily require specialized biosafety review beyond the requirements otherwise applicable to the experimental system, and we recommend that the Delegated Review mechanism described in Section IV-3 be applied to such work.

12. The scope of the draft Policy includes toxins listed as Select Agents, and research activities involving these materials would require IBC review and approval under Section IV-2, while research with biological toxin proteins not on the Select Agent list may be approved by Delegated Review under Section IV-3. We support this overall approach; however, we request refinement of the Policy with the following recommendations.

    a. **Recommendation 1:** Allow research activities using exempt amounts of Select Agent toxins to be approved by Delegated Review. Most institutions have already developed effective internal biosafety oversight mechanisms for handling these exempted materials. Integrating those internal oversight mechanisms into the Delegated Review process would allow IBCs to focus on the higher-risk Select Agent work.

    b. **Recommendation 2:** Either publish a list of biological toxins that fall within the scope of the Policy or use a threshold toxicity value as a risk-based factor for determining whether a biological toxin requires oversight by the Policy. We further recommend that biological toxins that have an LD_{50} greater than 1000 µg/kg be exempt from this Policy.

13. The scope of the draft Policy includes cells, viruses, or organisms, other than plants, that have been genetically modified. It is assumed that animals are included as organisms, but it is not clear what is considered an animal under this Policy.

    a. **Recommendation:** Use a definition of animal that is consistent with the Guide for the Care and Use of Laboratory Animals, which has been adopted by the NIH Office of Laboratory Animal Welfare, and which defines animals as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

14. The draft Policy indicates that the effective date will be 6 months from publication of final Policy, and that applicability includes ongoing work. It is unclear how ongoing work will be impacted by the new review and approval requirements. Work that was not subject to IBC oversight according to the NIH Guidelines may have been approved via voluntary institutional biosafety oversight mechanisms.

    a. **Impact:** Work that was approved by a Biosafety Officer (or other institutional biosafety oversight) and now requires a higher level of review by the IBC would need to cease until IBC approval is obtained. This would have a significant negative impact on a large number of projects that are suddenly subject to new oversight, thereby wasting grant money and setting back important research projects.

    b. **Recommendation:** Require activities that have not received approval by a Biosafety Officer or other institutional biosafety oversight mechanism to be reviewed and approved according to the final Policy within 6 months of the publication of the final Policy. For activities that have received approval by a Biosafety Officer or other institutional biosafety oversight mechanism, allow the existing approval to remain in place until such time as de novo registration is required (see point 2 regarding our recommendation to allow 5-year term limits for IBC registration approvals).

187. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Some scope of work requiring IBC review is not well defined, and these definitions should be tied to biosafety hazard.
-Research with prions or other self-aggregating proteins
-Research with well-characterized cell lines
-Primary cells that may be contaminated by adventitious agents.
It is unclear if this would include ALL work with primary human cells or NHP cells or tissues.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It is uneccessary to publically post incident reports along with PI and funding information. This will decrease the amount of reporting.

Meeting minutes template is way too long and overdetailed. Most of the information is not important to each meeting.

6. Other feedback relevant to this resource: Research that was previously exempt from IBC review under NIH Guidelines Section F now appears to require IBC review and approval prior to initiation, including work with all transgenic organisms and plasmids. This need additional clarification as it would require anyone working at an institution to have an IBC protocol.

188. Biotechnology Innovation Organization (BIO)

I am responding: On behalf of an organization

Name: Praneel Jadav

Name of Organization: Biotechnology Innovation Organization (BIO)

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: BIO-Response-NIH-RFI-Draft-Biosafety-Policy-10.19.26-vFINAL.pdf

October 19, 2026

Lyric Jorgenson, Ph.D.
NIH Associate Director for Science Policy
6705 Rockledge Drive, Suite 630,
Bethesda, MD 20892

Re: Notice Number: NOT-OD-26-112

Request for Information: Draft NIH Biosafety Policy for Research Involving Biohazards

Dear Dr. Jorgenson,

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments on the National Institutes of Health (NIH) Draft Biosafety Policy for Research Involving Biohazards. BIO and our member companies share NIH's commitment to ensuring that biomedical research is conducted safely, responsibly, and securely. Strong biosafety practices are essential to protecting researchers and the public, maintaining confidence in the biomedical research enterprise, and ensuring that the United States remains prepared to respond to biological threats.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies, all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO membership includes companies developing vaccines, therapeutics, diagnostics, and other medical countermeasures (MCMs) to prevent, detect, and respond to naturally occurring infectious diseases and chemical, biological, radiological, and nuclear threats.

MCM research presents a particularly important consideration for the proposed Policy. Research involving pathogens is often necessary to understand biological threats and to develop the vaccines, therapeutics, and diagnostics required to protect Americans from them. Federal biosafety policy must therefore appropriately manage legitimate biological risk while preserving the ability of responsible entities to conduct necessary research into innovations that could mitigate those same threats.

BIO supports NIH's objective of modernizing biosafety oversight and establishing risk-based safeguards. However, the proposed expansion of the NIH Guidelines into a substantially broader policy governing research involving biohazards raises important questions regarding

scope, applicability, duplication with existing oversight frameworks, and the potential effect on U.S. biotechnology competitiveness. BIO recommends NIH more narrowly and clearly define the research and entities subject to the Policy, establish explicit mechanisms to avoid duplicative oversight, and ensure that requirements are proportionate to the risks presented by individual research activities.

Scope and Definitions Must Be Clear, Risk-Based, and Operationally Workable

The proposed Policy represents a significant expansion from the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The draft Policy would apply to all biomedical research in laboratory settings involving defined biohazards and would expand oversight to wild-type biological agents that cause human disease, genetically modified cells, viruses and organisms, toxins, prions, and other covered materials.

BIO recommends that NIH further refine this scope before finalizing the Policy.

Terms that determine whether research falls within a federal oversight framework must provide sufficient specificity for researchers and companies to determine their obligations prospectively. Definitions such as “biomedical research,” “biohazard,” “potential risk to human health,” and “genetically modified” could encompass an overly broad range of research routinely conducted safely throughout the biotechnology sector.

This is particularly relevant to MCM development. By its nature, MCM research may involve pathogens, pathogen components, genetically modified systems, challenge models, primary cells, platform technologies, or other biological materials necessary to characterize threats and evaluate potential countermeasures. The presence of one of these materials should not by itself establish that research presents a level of biosafety risk warranting heightened oversight. One key example of potential risk to non-recombinant work with wild-type biological agents would be routine research involving wild-type seasonal influenza viruses to evaluate yearly vaccine candidates. This research would become subject to new Institutional Biosafety Committee (IBC) review and approval requirements under the Policy’s proposed Section IV-3, even when conducted under established biosafety protocols. Such requirements could introduce additional administrative burdens without necessarily improving biosafety outcomes and slow down critical research needed to protect Americans every year from a very common biological threat.

BIO recommends that NIH narrow and clarify the proposed Policy’s scope to ensure that oversight is proportionate to the actual biosafety risks associated with specific research activities, rather than broadly capturing research based solely on the biological materials involved. NIH should establish clear, scientifically grounded definitions and risk-based criteria that distinguish non-risky biomedical research from activities warranting heightened oversight. This approach would be consistent with the protocol-driven risk assessment principles that have long underpinned U.S. biosafety practice.

NIH Should Clarify Which Private Sector Entities and Research Activities Are Subject to the Policy

BIO is particularly concerned about the proposed applicability of the Policy. As currently drafted, the Policy states that it applies to NIH-supported research regardless of funding level or mechanism, as well as non-NIH funded research conducted at an institution receiving any NIH funding. The latter is particularly problematic due to the unwarranted expansion of the Policy's scope to research funded independently of the agency, potentially imposing duplicate or conflicting oversight obligations and discouraging private sector partnerships with NIH-funded institutions. NIH should clarify how this provision would operate for biotechnology companies and complex public-private research arrangements.

Biotechnology research increasingly occurs through networks of companies, academic collaborators, contract research organizations, contract development and manufacturing organizations, clinical research organizations, government laboratories, and other partners. A biotechnology company may participate simultaneously in NIH-supported research, privately financed product development, BARDA-supported MCM programs, Department of War programs, and FDA-regulated clinical development. It is therefore important that NIH clearly define the organizational boundaries of an "institution" for purposes of the Policy and explain whether receipt of NIH funding for one discrete program could subject unrelated or privately funded research elsewhere within a company or corporate organization to NIH oversight. BIO recommends NIH establish a clear nexus between NIH funding and research subject to the Policy. NIH should avoid creating circumstances in which receipt of a single NIH award effectively extends NIH jurisdiction across an organization's unrelated research portfolio. Without greater clarity, companies may face substantial uncertainty regarding whether accepting NIH funding for one research program creates additional complexities including compliance requirements for other research activities. For many innovators, especially small and emerging biotechnology companies, this uncertainty may become a factor in determining whether to seek or accept NIH funding.

Oversight Should Be Proportionate to Risk Rather Than Predicated on the Presence of a Covered Biological Material

BIO proposes NIH maintain a risk-based approach to oversight, reporting, and review requirements. However, a risk-based framework is only effective if low and moderate risk research can move efficiently through the system and if categories are sufficiently clear to produce consistent outcomes across institutions. The proposed Policy would require IBC review for a broad range of activities, including research involving genetically modified cells, viruses or organisms, Risk Group 3 and 4 (RG3 and RG4) wild-type agents, certain primary cells, and certain clinical research. Delegated review would also be required for activities including RG2 wild-type agents, well-characterized cell lines, genetically modified RG1 agents, and certain plasmids and vectors. The breadth of these categories could significantly increase the volume of research requiring IBC review without necessarily producing a commensurate improvement in biosafety.

BIO recommends NIH establish clearer exclusions or streamlined pathways for well-characterized research activities where risks are already understood and effectively managed. The goal should be to concentrate limited biosafety expertise and institutional resources on

research presenting meaningful risk rather than expanding administrative review across large categories of routine biomedical research. This is particularly important for MCM developers, where speed and continuity of research can directly affect national preparedness.

Avoid Layering Duplicative Requirements Across the Federal Research Enterprise

Biotechnology companies already operate within an extensive system of federal and institutional requirements governing research safety, biosecurity, clinical development, laboratory practices, research involving recombinant or synthetic nucleic acids, select agents and toxins where applicable, human and animal research, and FDA-regulated product development.
BIO appreciates that the draft Policy recognizes that research under the regulation or purview of another federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained. This principle should be strengthened and operationalized. NIH should establish clear reciprocity and reliance mechanisms identifying when existing federal review satisfies corresponding requirements under the Policy. Companies should not be required to conduct duplicative assessments, submit identical information to multiple federal entities, or undergo multiple institutional reviews addressing the same underlying biosafety risk. Duplicative oversight increases already substantial administrative costs and resources away from biosafety activities and can delay critical research without improving safety outcomes.

Federal agencies should also work toward common terminology, risk assessment methodologies, documentation requirements, and reporting expectations. This is especially important as the U.S. Government continues to update multiple policies affecting biological research. A succession of overlapping requirements, each individually intended to strengthen safety or security, can collectively create substantial administrative burden and uncertainty if they are not harmonized. BIO recommends recognizing existing mature biosafety programs and allowing flexibility for institutions to demonstrate equivalent governance, risk assessment, and oversight processes.

The appropriate objective should be an integrated federal framework in which requirements complement rather than duplicate one another. The delegated review provisions that already exist should remain appropriately limited to clearly defined low-risk activities.

Protect Proprietary, Security-Sensitive, and Confidential Research Information

BIO also encourages NIH to carefully evaluate the proposed transparency requirements for IBC materials and incident reporting. Transparency can strengthen confidence in biosafety oversight, but biotechnology research frequently involves proprietary information, confidential development programs, sensitive intellectual property, and information with potential biosecurity implications.

Public disclosure requirements should therefore be narrowly tailored to the public safety purpose they are intended to serve and include clear protections for proprietary, confidential, security-sensitive, and prepublication scientific information.

Companies should not be required to choose between participating in federally supported research and protecting commercially sensitive technologies or information that should not be broadly disseminated for security reasons. If commercially sensitive information does not have robust protections, companies would be unlikely to participate in federally supported research.

Biosafety Policy Must Strengthen, Rather Than Weaken, U.S. Biotechnology Competitiveness

Biosafety and U.S. economic competitiveness should be mutually reinforcing objectives. The United States has historically led biomedical innovation because of its combination of world-class research institutions, innovative biotechnology companies, strong intellectual property protections, sophisticated capital markets, and productive partnerships between government, academia, and industry. Federal biosafety policy should preserve these advantages.

Biomedical R&D is increasingly global. Research programs, investment, scientific talent, and partnerships can move between jurisdictions. If U.S. requirements become significantly more complex, costly, uncertain, or time-consuming than those of international competitors without a corresponding improvement in safety, the United States risks discouraging domestic research and investment and ceding ground as the leader in biotechnological research and development.

This risk is particularly consequential for MCM research. Many MCM programs already face challenging economics because products intended for rare biological threats have limited traditional commercial markets. Additional fixed compliance costs, delays, and uncertainty can have an outsized effect on decisions to initiate or continue these programs. Moreover, innovators developing platforms for MCMs could transition their technology to another indication with more certainty and less risk.

For small biotechnology companies, even modest increases in research timelines and compliance costs can affect capital requirements and investment decisions. Over time, these cumulative burdens can reduce the number of companies willing to conduct research on high-consequence pathogens and emerging infectious diseases. Such an outcome would not improve U.S. biosecurity. It could instead reduce domestic expertise, weaken the MCM pipeline, and shift strategically important research capabilities to jurisdictions where the United States has less visibility and influence. Ultimately, this could delay the development of lifesaving MCMs, leaving Americans more vulnerable to an evolving biothreat landscape.

NIH should therefore evaluate the economic and competitiveness impacts of the proposed Policy as part of its implementation process, including effects on small and mid-sized companies, participation in federally supported research, MCM development timelines, and the location of biotechnology R&D.

Recommendations

BIO recommends that NIH revise the draft Policy to:

1. Narrow and clarify the definitions that determine the Policy's scope, particularly “biomedical research,” “biohazard,” “potential risk to human health,” “genetically modified,” and “institution.”

2. Establish a clear nexus between NIH funding and research subject to NIH oversight so that receipt of NIH funding for one program does not automatically bring unrelated privately funded research within scope.

3. Preserve a genuinely risk-based approach in which the level of oversight is determined by the specific risks presented by an experiment rather than the presence of a covered biological material.

4. Create exclusions or expedited review mechanisms for well-characterized, lower-risk research.

5. Establish formal reliance and reciprocity mechanisms for research already subject to appropriate oversight by FDA, BARDA, the Department of War, or other federal entities.

6. Conduct a specific assessment of the Policy's impact on MCM research and development and ensure that implementation does not undermine federal objectives to expand the domestic MCM industrial base.

7. Provide flexible compliance mechanisms and technical assistance for small and emerging biotechnology companies, including access to external or shared IBC resources.

8. Ensure public transparency requirements contain strong protections for proprietary, confidential, intellectual property, and security-sensitive information.

9. Harmonize the Policy with existing and emerging federal biosafety, biosecurity, research security, and product development requirements to prevent duplicative or inconsistent compliance obligations.

10. Evaluate the cumulative economic and competitiveness effects of the Policy, including whether additional requirements could discourage domestic investment or move strategically important research outside the United States.

Conclusion

BIO supports NIH’s goal of modernizing the nation’s biosafety framework and ensuring that biomedical research is conducted safely, securely, and responsibly. Achieving that objective requires a framework that is scientifically grounded, proportionate to risk, operationally feasible, and coordinated with the broader federal research and regulatory enterprise.

These principles are especially important for medical countermeasure research. The United States depends on biotechnology companies willing to conduct difficult, capital-intensive research against biological threats for which traditional commercial markets may not exist.

Federal policy should encourage responsible participation in this research while applying appropriate safeguards, not create cumulative barriers that unintentionally reduce the number of organizations willing or able to undertake it.

Clear definitions, targeted oversight, regulatory harmonization, and practical implementation can strengthen biosafety while preserving the innovation ecosystem necessary for U.S. biodefense and national health security. BIO looks forward to working with NIH to develop a final policy that protects the American public while maintaining U.S. leadership in biomedical innovation and medical countermeasure development.

BIO appreciates the opportunity to submit comments in response to this RFI and looks forward to partnering with NIH as the agency aims to modernize and strengthen biosafety policies to keep pace with the evolving biothreat landscape.

Sincerely,

/s/

Phyllis Arthur

Executive Vice President, Chief of Global Health

189. NYSDOH Wadsworth Center

I am responding: On behalf of an organization

Name: David Hill

Name of Organization: NYSDOH Wadsworth Center

Type of Organization: Government Agency

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Public Health Life Sciences Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See comments in attachment provided.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See comments in attachment provided.

3. Continued utility of Risk Groups: See comments in attachment provided.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: See comments in attachment provided.

Uploaded File: NIH-Biosafety-Policy-Response_final_10-15-2026.pdf

Description: Wadsworth Center comments on NIH Draft Biosafety Policy for Research Involving Biohazards

NEW YORK STATE | Department of Health
Wadsworth Center

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

October 15, 2026

NIH Office of Science Policy
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

Dear National Institutes of Health Office of Science Policy,

The New York State Department of Health Wadsworth Center appreciates the opportunity to comment on the National Institutes of Health (NIH) Draft Policy for Research Involving Biohazards and supports NIH's efforts to strengthen biosafety oversight through a risk-based approach that reflects the nature of the research being conducted.

Please see the attached comments and recommendations regarding the NIH Draft Biosafety Policy.

Sincerely,

Dr. Leonard Peruski

Director, Wadsworth Center

Attachment

Attachment: NYSDOH Wadsworth Center Comments on Draft Policy for Research Involving Biohazards

1. RFI Questions
   a. *Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed*.

      Comment #1: The current definition of biomedical research leaves some uncertainty about what research activities are covered. Public health laboratories conduct applied research to improve the testing and detection of agents of public health concern, a critical activity for effectively responding to emerging biological and chemical threats. These activities directly support public health response efforts and should not unintentionally trigger additional research oversight requirements that could delay implementation of needed testing.

      Recommendation: NIH should clarify the definition of biomedical research to distinguish applied research conducted as part of Public Health Laboratory operations from research intended to be covered by the policy, making it clear that test development and improvements performed in Public Health Laboratories are outside the scope of the policy.

      Comment #2: The term "biohazard" should be clearly defined under General Definitions with the other key terms used in the policy, not in Section II – Scope.

      Recommendation: NIH should define "biohazard" under General Definitions. We offer the following definition for consideration: Biohazard - Any of the following biological agents or materials that cause disease in humans or otherwise have known or potential risk to human health: 1) wild-type biological agents,i.e., virus, bacteria, fungi, or parasites; 2) cells, biological agents, or organisms, other than plants, that have been genetically modified; 3) toxins, prions, and other self-aggregating proteins; or 4) cells or organisms, other than plants, containing biological agents or materials from categories 1, 2, or 3 above.

   b. *Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL)*.

      Comment #3: The existing risk group classification system as defined in the current NIH Guidelines is too limited in scope to have utility in conducting risk assessments involving communicable agents with potential for risk to the community. The expanded definition of risk groups provided by the World Health Organization goes

further in trying to capture the risk to the community, but it still doesn't adequately account for pathogens with the greatest risk for societal consequences, including pathogens with pandemic potential. As an example, the 1918 H1N1 influenza virus, 1957-1968 H2N2 influenza virus, and H5N1 highly pathogenic avian influenza virus are collectively classified as Risk Group 3 influenza viruses in Appendix G of the current NIH Guidelines, with requirements for BSL-3 enhanced mitigation measures. However, the WHO definition of a risk group 3 pathogens indicates that it "does not ordinarily spread from one infected individual to another" and has "low community hazard". This discrepancy in being able to accurately characterize the relative societal risk of communicable agents using the existing risk group classification systems demonstrates the need for a separate, distinct hazard characterization nomenclature specific to the potential for a communicable wild-type pathogen, or modified pathogens, to cause a negative consequence to society.

Recommendation: Develop a separate, distinct hazard characteristic nomenclature that is specific to determining the relative societal risk of pathogens based on population susceptibility, route of transmission, ability for pre-symptomatic or asymptomatic spreading, treatment options, and other agent hazard characteristics appropriate for conducting a societal risk assessment of communicable pathogens.

c. *Feedback on the implementation resources and areas in which additional guidance would be beneficial*.

Comment #4: The background section of the policy notes that additional information about requirements for containment practices, occupational health plans, and training for research with RG3 influenza viruses (currently articulated in Section II-D-7 and Appendix G-II-C-5 of the NIH Guidelines) will be shared with the research community through implementation resources. However, those mitigation measures are currently limited to high-risk strains of influenza viruses with societal risk.

Recommendation: NIH should ensure that the BSL-3 enhanced mitigation measures currently described in Section II-D-7 and Appendix G-II-C-5 of the current NIH Guidelines serve as default BSL-3 enhanced requirements for RG3 influenza viruses and other communicable pathogens with potential for significant societal consequence unless otherwise determined to be unnecessary by the local IBC in consultation with NIH.

2. Section II – Scope

Comment #5: It is not clear what the authors mean when they state, "Any research subject to this Policy that is also under the regulation or purview of another federal

agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained."

Recommendation: Clarify from whom, specifically, “approvals and other applicable clearances” need to be obtained before research may proceed under the oversight of another federal agency.

3. Section II - General Definitions

Comment #6: The acronym GDMO is used throughout the body of the policy but never defined. Only Gene Drive is defined.

Recommendation: Add Gene Drive Modified Organism (GDMO) to the definitions sections and provide an appropriate definition to supplement the existing definitions provided for Gene Drive and Genetic modification.

Comment #7: Arthropod Containment Levels are not captured in the scope of this policy.

Recommendation: Revise the definition of laboratory research to include arthropod containment facilities as follows: Laboratory research - Research conducted within Biosafety Level/Animal Biosafety Level/Arthropod Containment Level (BSL/ABSL/ACL) 1-4containment facilities, including spaces such as vivarium, core facilities, insectaries, or clinical settings. It does not include the deliberate release of a biohazard outside of biocontainment, such as field release research. Update all references to BSL2/ABSL2, BSL3/ABSL3, etc. throughout the policy to include reference to the applicable ACL, i.e., BSL3/ABSL3/ACL3.

4. Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)

Comment #8: The responsibility described for the 6th bullet unnecessarily repeats part of the 5th bullet.

Recommendation: Revise the first sentence of the 6th bullet as follows, “Petitioning NIH to lower the minimum containment for research involving RG3 and RG4 agents that have not previously been approved by NIH.”

Comment #9: It is misleading to say that the categories of reportable incidents listed under Section II-B all pose a significant risk to human health.

Recommendation: Replace the phrase "that pose a significant risk to human health” with “that have the potential for significant risk to human health" in both the policy and on the incident report form.

Comment #10: The criteria for determining a "potential laboratory-acquired infection" under the reporting requirements are not provided.

Recommendation: Provide specific criteria for what would be considered a "potential laboratory acquired infection" or revise to limit the reporting requirement to confirmed laboratory-acquired infections determined through diagnostic testing.

Comment #11: The wording of the BSL-3/ABSL-3 and BSL-4/ABSL-4 reporting requirement for "potential exposures" should be modified to align with the definition of "occupational exposure" in the select agent regulations for consistency and to eliminate any uncertainty related to potential exposure vs. occupational exposure requiring reporting.

Recommendation: Revise the "exposure" reporting requirement for BSL-3/ABSL-3 and BSL-4/ABSL-4 to read as follows: Any occupational exposure defined as any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to pathogens at BSL-3/ABSL-3/ACL-3 or BSL-4/ABSL-4 that may result from the performance of an employee's duties. Any exposure event that results in the activation of post-exposure medical treatment or surveillance protocols would be considered an occupational exposure. To simplify, the definition of "occupational exposure" could be added to the General Definitions section so that the statement here could be "Any occupational exposure."

Comment #12: The wording of the BSL-3/ABSL-3 and BSL-4/ABSL-4 reporting requirement for releases should be modified to align with the definition of "release" in the select agent regulations for consistency and to eliminate any uncertainty related to "potential releases vs. releases that need to be reported.

Recommendation: Revise the BSL-3/ABSL-3 and BSL-4/ABSL-4 "release" reporting requirement to read as follows, “Any release defined as any discharge of a BSL-3/ABSL-3/ACL-3 or BSL-4/ABSL-4 pathogen outside primary containment devices (e.g., biological safety cabinets, centrifuge safety cups, etc.) or secondary barriers (e.g., HEPA exhaust systems and other biocontainment facility boundaries).” If the definition of "release" is moved to the General Definitions section, the policy can simply say "Any release" under the reporting section.

Comment #13: The wording of BSL-2/ABSL-2 exposure reporting requirements should be aligned with the proposed definition of occupational exposure for BLS-3/ABSL-3/ACL-3 and BSL-4/ABSL-4 exposure reporting.

Recommendation: Revise the BSL-2/ABSL-2 exposure reporting requirement to read as follows, “Any incidents involving occupational exposures at BSL-2/ABSL-2/ACL-3 that require agent-specific post exposure medical treatment beyond basic first aid.”

Comment #14: The BSL-3/ABSL-3 and BSL-4/ABSL-4 reporting expectations for biological agent inventories should use terminology consistent with the select agent program for consistency to avoid uncertainty about what needs to be reported.

Recommendation: Replace the biological agent reporting wording as follows, “Theft or loss of biological agents that may have public health consequences.”

Comment #15: The reporting expectations for "compliance violations" at any BSL/ABSL is too vague and open ended. This reporting expectation needs to be specific to avoid over reporting of minor compliance issues.

Recommendation: Revise the compliance violation reporting requirements to be limited to serious compliance violations associated with this policy, such as 1) failure to obtain or maintain IBC approval; or 2) failure to obtain NIH approval for lowering biocontainment for research.

Comment #16: The wording of the reporting exemption for minor spills of low-risk agents does not specify if the breach is at the primary or secondary containment barrier.

Recommendation: Revise to clarify that the reporting exemption applies to minor spills where a breach of secondary containment is not involved.

Comment #17: The incident report posting requirement states that all incident reports need to be posted on a public facing webpage.

Recommendation: Clarify that only NIH incident reports need to be posted on a public-facing webpage, not “all incident reports”.

Comment #18: The requirement for reporting all incidents within 24 hours or as soon as the institution becomes aware of the incident is an unreasonable expectation (e.g., for an incident that happens at the end of a Friday workday).

Recommendation: Replace the 24-hour reporting requirement with "by the close of the next business day or as soon as the institution becomes aware of the incident".

5. Section IV-1 - Research That Requires NIH and IBC Approval Before Initiation

Comment #19: During the NIH regional listening sessions, it was stated that one of the goals of the biosafety modernization effort was to recalibrate oversight to risk. However, there are clear examples of wild-type pathogens that are known for their pandemic potential (eg., RG3 influenza pathogens currently described in Appendix G of the NIH Guidelines) that are not included under Section IV-1 *Research That Requires NIH and IBC Approval Before Initiation* to ensure that the minimum

biosafety containment, occupational health, and exposure response mitigation measures are in place before the research activities with potential for societal risk can begin.

Recommendation: NIH should reconsider including all laboratory activities that generate, use, reconstitute, or transfer an eradicated or extinct pathogens with pandemic potential (PPP) to Section IV-1, since these PPPs may pose a significant threat to public health, the capacity of health systems to function, or national security and, therefore, warrant Federal oversight to ensure consistency in the mitigation measures being utilized for all laboratory manipulations involving these PPPs.

6. Section V - Risk Assessment and Mitigation for Research Involving Biohazards

   Comment #20: Section V makes no reference to the need for risk-based occupational health programs and post-exposure response protocols when it comes to selecting and establishing mitigation measures for research involving biohazards, particularly those with high risk to individual workers and/or society.

   Recommendation: Add “occupational health programs” and “exposure response protocols” as additional examples of key components of the risk mitigation strategy to emphasize their importance.

7. Section V-A - Requirements and Considerations for Risk Assessment of the Characteristics of the Biohazard

   Comment #21: The statement under Section V-A that "Biological agents that cause disease in humans are classified into four RGs based on pathogen characteristics and population impacts." is somewhat of a false assumption (See comment #3).

   Recommendation: NIH needs to develop a separate, distinct hazard characteristic nomenclature that is specific to determining the relative societal risk of pathogens based on population susceptibility, route of transmission, ability for pre-symptomatic or asymptomatic spreading, treatment options, and other agent hazard characteristics appropriate for conducting a societal risk assessment of communicable pathogens. This new nomenclature should be referenced within this policy as appropriate to communicate its role in facilitating risk assessments.

8. Section V-E - Risk Mitigation Strategies and Laboratory Containment

   Comment #22: The basis for assigning a minimum BSL for experiments involving mutated or recombinant influenza viruses is the RG of the virus that was the source of the of the majority of segments in the virus. However, the current risk group classification system does not adequately characterize the potential societal risk

which may be the key risk factor for determining the need for any enhanced mitigation measures. Additionally, it is not clear why a minimum BSL is being established for mutated or recombinant influenza viruses, but not coronaviruses (e.g., SARS-CoV-1 or SARS-CoV-2 virus) where a similar level of individual worker risk and societal risk could be of concern for research including mutated or recombinant viruses.

Recommendation: Revise the section on minimum BSL criteria to reflect the appropriate societal risk criteria or updated classification system on which these minimum BSL recommendations should be made, not the existing risk group classification system. Additionally, consider expanding the scope of research that requires minimum BSLs to include other communicable pathogens with potential for enhanced societal risk from mutated or recombinant viruses.

Comment #23: The requirement for conducting experiments with viruses containing genes from RG3 influenza viruses with pandemic potential at BSL-3 enhanced containment with the additional requirement for an occupational health plan, does not specify the detailed expectations of these minimum BSL-3 enhanced requirements.

Recommendation: NIH should ensure that the BSL-3 enhanced mitigation measures that will be included in the implementation resources serve as the default requirements for BSL-3 enhanced for RG3 influenza viruses, as well as for other communicable pathogens with potential for significant societal consequence, unless otherwise determined to be unnecessary by the local IBC in consultation with NIH.

190. Nancy Rolstad

I am responding: On behalf of myself

Name: Nancy Rolstad

Name of Organization: University of Minnesota

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Specialist

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): All biomedical sciences

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Mine and many other institutions and professional societies have provided detailed comments that cover all my concerns but I'm writing to especially note one concern. Funding. Funding for coverage for all the proposed changes is lacking. We are already strapped and it is only getting worse as our institution must slash hundreds of millions of dollars. Staffing shortages and hiring freezes are not going to allow timely implementation of these proposed changes. Boots on the ground biosafety is the key to compliance and keeping research safe. Please make sure adequate funding will be instituted to help these proposed changes be implemented. Biosafety professionals are dedicated to compliance but we need additional help to make it happen. Thank you.

191. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: research operations

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Expand the stated purpose: Recommend explicitly including potential risks to the environment and animals to ensure the policy addresses impacts beyond human health.

Clarify self-aggregating proteins: Define “self-aggregating proteins” and provide risk assessment guidance to help institutions determine when additional biosafety oversight is warranted. Clarify whether all relevant proteins can be identified and how institutions should assess proteins with unknown or incompletely characterized properties.

Extend the implementation timeline: Recommend extending the implementation period to 12 months following the effective date to allow institutions sufficient time to evaluate existing programs, revise policies and procedures, restructure responsibilities, and secure additional resources as needed.

Clarify genetic modification by chemical or radiological means: The definition of genetic modification includes “the introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.” Recommend removing or clarifying the references to chemical and radiological means and providing specific guidance on when such activities fall within the policy's scope. Radiological hazards are already subject to separate regulatory oversight, including NRC requirements where applicable. Without clear boundaries, this provision could create duplicative reviews and responsibilities.

Clarify the definition of laboratory research: The policy defines laboratory research as work conducted in BSL/ABSL-1 through BSL/ABSL-4 facilities, including vivarium, core facilities, and clinical settings. Recommend clarifying what qualifies as a “clinical setting.” Clinical areas, such as patient rooms and operating rooms, typically do not have an assigned biosafety level. Guidance is needed to determine when research conducted in these areas falls within the policy's scope.

Clarify clinical research terminology: Define terms such as “shedding” and “higher manipulations” and provide examples to support consistent interpretation across institutions and research settings.

Allow flexibility in IBC meeting documentation: The requirement to prepare and approve IBC meeting minutes no later than the next convened meeting may create additional administrative burden. Recommend clarifying the approval process and allowing reasonable flexibility to accommodate institutional meeting schedules and workflows.

Clarify or reconsider de novo review requirements: Recommend eliminating or limiting de novo reviews when existing institutional review processes adequately address the risks. Requiring de novo review may create a significant administrative burden for IBCs and research teams by necessitating additional assessments, documentation, and approvals for activities that may already have been evaluated under established protocols. This could lead to duplicative reviews, increased processing times, and delays in research activities without a corresponding improvement in biosafety. If de novo review is retained, provide clear criteria defining when it is required and allow institutions to leverage existing risk assessments and approvals when appropriate.

Provide guidance for Biological Risk Groups (RGs): The NIH Guidelines classify agents into four Risk Groups based on their ability to cause disease in healthy adult humans. The BMBL uses risk assessment to inform recommended biosafety levels rather than serving as a comprehensive Risk Group classification list. Recommend developing guidance similar to the existing NIH Risk Group list that institutions can use as a reference. Not all agents included in the NIH Guidelines' Risk Group list are addressed in the BMBL, creating a need for a consistent reference to support institutional assessments.

Clarify Biological Safety Officer (BSO) responsibilities: A single BSO may not be sufficient to support the needs of large or complex institutions, where biosafety responsibilities are often distributed across multiple qualified staff members. Recommend allowing designated responsibilities to be performed by the BSO or an authorized designee to accommodate different institutional structures.

Clarify incident reporting pathways: The policy requires PIs to report incidents but does not clearly identify the appropriate reporting recipient or process. Recommend explicitly identifying the IBC as a reporting contact and clarifying the reporting pathway, including any additional institutional or federal reporting requirements.

Reconsider public-facing incident reporting: Posting incident details on a public-facing website may discourage reporting or undermine a culture of safety by creating concerns about reputational consequences. Recommend evaluating whether public disclosure is necessary and considering alternatives that promote transparency, accountability, and learning while protecting appropriate confidentiality.

Provide flexibility for institutional implementation: Recognize that institutions differ in size, staffing, research complexity, and existing oversight structures. Implementation guidance should allow institutions to establish processes that meet policy requirements without unnecessarily duplicating existing oversight functions.

Clarify whether human and non-human primate materials are in scope: The policy's incident-reporting language references post-exposure treatment for potential adventitious agents, such as non-human primate Herpes B virus or bloodborne pathogens. It is unclear whether this includes research involving human blood, other human materials, or non-human primate materials when no biological agent is deliberately involved in the research. For example, macaque research may involve animal procedures without the deliberate use of biological agents. Recommend clarifying which materials and activities are covered and which incidents require reporting.

Apply risk-based oversight to established transgenic organisms: Recommend clarifying whether routine research involving established transgenic organisms at BSL-1/ABSL-1, such as commonly used transgenic mouse strains and fruit fly lines, requires additional review. Consider exempting established, well-characterized organisms from de novo or additional review when no new hazards are introduced and existing institutional oversight adequately addresses the risks. Additional review could remain necessary when genetic modifications introduce novel or increased hazards.

Clarify reporting expectations for exposures: Distinguish between exposures involving biological agents deliberately used in research and exposures involving potential adventitious agents unrelated to the research. Provide clear examples of which scenarios require institutional reporting, NIH reporting, or both to ensure consistent interpretation and avoid unnecessary reporting.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Establish minimum qualifications and competency standards for the Biosafety Officer (BSO) role: The BSO is a specialized technical role requiring expertise in biosafety principles, biological risk assessment, regulatory requirements, containment practices, and incident investigation. Recommending that any institutional staff member can fulfill this role without defined qualifications or demonstrated competency is not best practice and may compromise the quality of biosafety oversight.

3. Continued utility of Risk Groups: Develop a standardized Risk Group reference to support risk assessments: Risk Group classification is a foundational starting point for biological risk assessment. It helps determine an agent’s potential to cause disease and informs the evaluation of appropriate containment measures and biosafety controls. The NIH Guidelines classify biological agents into four Risk Groups based on their ability to cause disease in healthy adult humans, while the BMBL uses a risk assessment approach to inform recommended biosafety levels rather than providing a comprehensive Risk Group classification list.

Recommend developing and maintaining a reference similar to the existing NIH Risk Group list. Not all agents included in the NIH Guidelines are addressed in the BMBL, creating gaps when institutions evaluate agents not specifically covered by either resource. A standardized reference, supplemented by guidance for unlisted agents, would provide a practical starting point for institutional assessments and reduce administrative burden.

This reference should support—not replace—a thorough, activity-specific risk assessment, as the appropriate biosafety level and controls depend on additional factors, including the nature of the work, route of exposure, procedures performed, and available risk mitigation measures.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Create an incentive for non-funded institutions to comply with this policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Remove PI names from incident reports and public disclosures: Recommend removing the PI's name from incident reports intended for public disclosure and reporting incidents in an aggregated, anonymized format. Incidents are an inevitable part of research, and the primary goal of biosafety oversight should be to understand what happened, identify contributing factors, and implement corrective actions to prevent recurrence. Including the PI's name in public reports can create the perception of assigning blame or singling out individuals, which is inconsistent with a strong, proactive safety culture.

Public identification may discourage PIs and research staff from reporting incidents, near misses, and potential hazards, limiting opportunities to identify trends, address systemic issues, and prevent future injuries or exposures. Effective incident reporting should encourage transparency and continuous improvement rather than create fear of reputational consequences.

Recommend collecting incident data systematically and publishing anonymized, aggregated summaries of incidents, trends, and corrective actions, similar to OSHA's approach to summarizing workplace injury and illness data. This would promote transparency, accountability, and organizational learning while protecting individual identities and encouraging timely reporting. The focus should be on understanding risks and preventing recurrence, not assigning blame.

6. Other feedback relevant to this resource: Increase implementation to 12 months.

192. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As Biosafety professionals, our comments reflect our wet-lab and administrative experience to address practical operational needs for compliance under the new Policy. We appreciate the opportunity to provide feedback.

While we strongly support Delegated Member Review (Section IV-3) to streamline low-risk research, the Policy needs precise definitions. Expanding IBC purview to cover all wild-type RG-2 agents, clinical trials, and non-recombinant toxins significantly increases administrative workload. Without additional qualified Biosafety Officers (BSOs) and support staff, this expanded scope will create severe review bottlenecks. To maintain safety standards without stalling research, NIH should provide robust implementation grace periods and scalable guidance. In addition, rather than mandating rigid templates, NIH should allow institutions to adapt the forms to their existing software, whilst keeping required elements. Reserving full IBC review for higher-risk traits, gene drives, and environmental release ensures resources remain focused on real risk.

For Clinical Trial Oversight Scope (Section IV-2), there appears to be expanded clinical trial review from RG-2 and above agents, to any agent that sheds/replicates. This may create jurisdictional confusion between IBCs and IRBs. NIH must provide in more specific detail with examples of what studies require full IBC review.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): As Biosafety professionals we strongly support the proposed tiered oversight framework, yet the policy needs clearer practical guidance to empower IBCs to perform their risk assessments. Guidance should account for local facility capabilities, personnel expertise, occupational health infrastructure, and community considerations.

Review bottlenecks are a real concern: Section II indicates the Policy will apply to all ongoing research as of the effective date (6-month effective date). Attempting to re-review or retroactively re-classify thousands of active, approved protocols simultaneously will severely overwhelm IBC administrative

capacity, stall ongoing research, and create massive administrative backlogs. The proposed time-frame is insufficient for institutions to overhaul electronic compliance systems, update institutional biosafety manuals, retrain faculty and staff, and reconfigure websites. Even the DOD had to suspend implementation of their Cybersecurity Certification requirements due to compliance costs. NIH should extend the implementation timeline to at least 12 to 18 months from the publication of the final Policy, and incorporate a "grandfathering" clause or transitional exemption for currently approved, active research protocols and well-established models.

3. Continued utility of Risk Groups: Risk Groups (RGs) offer a clear baseline for assessing intrinsic hazard, but the Policy should rely on the Biosafety in Microbiological and Biomedical Laboratories (BMBL) rather than creating another version of a less frequently updated Appendix B of the NIH Guidelines. To prevent delays during public health emergencies or with novel pathogens, local IBCs need explicit authority to provisionally assign temporary containment levels while federal determinations are pending. Restricting direct NIH approval (Section IV-1) to high-risk novel research keeps federal oversight focused on true uncertainties rather than bottlenecking agents (or agent families) with long histories of safe use.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary compliance for non-NIH-funded or international institutions lacks enforcement, allowing unmonitored entities to conduct high-risk research or withhold incident reports without regulatory consequences. Implementing this Policy requires significant administrative effort and at a significant cost (personnel and IT systems), non-funded entities have little incentive to participate voluntarily. To solve this, NIH should establish an accreditation program similar to AAALAC for animal research. Requiring this accreditation for journal publishing, private investment, joint ventures, or international federal funding would incentivize non-funded institutions to adopt NIH-level biosafety standards.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The Draft Minute and Incident Reporting templates should be recommended, not mandated (except for required elements). While pre-made templates can be helpful for general standardization, they constrain workflows. IBC meetings tend to be dynamic and can vary in structure, a rigid template forces discussions to fit a format that doesn't quite match how the meeting unfolds. Additionally, the pre-built templates in IBC and EHS software have technical limitations and constraints that do not match the mandated template; that restricts how IBCs will capture and organize notes effectively.

As Biosafety professionals we fully support transparency and accountability regarding institutional safety, but we have serious concerns regarding the requirement to publicly post all final incident reports on Websites. Specifically, this mandate creates significant risks: 1) Incident investigations inherently involve sensitive details regarding specific physical spaces and personal health information (PHI) of individuals involved. Even with redactions or vagueness, the broad public availability of these details could lead to privacy breaches or discourage complete disclosures. 2) The fear of public exposure is a well-documented deterrent in safety culture. If researchers believe minor or sensitive incidents will be published on a public-facing webpage, it will disincentivize transparent reporting, ultimately undermining the very safety and compliance goals this Policy aims to achieve. 3) There may be a subset of incidents which fall under states' quality assurance privilege laws, with confidentiality protections for certain materials. 4) Our institution already maintains transparency through our IBC meeting minutes, which includes incident reporting which are publicly available on our website and provide adequate

oversight and public awareness without compromising individual privacy or research security. In addition, there are reporting requirements to local public health authorities. 5) Comprehensive incident response and root cause analysis takes time and a 24-hour reporting period is not feasible; this may result in reporting that is speculative and, as a result, of limited value. 6) We recommend striking the requirement for public-facing incident report postings and instead employ a model similar to the OSHA Form 300A, where incidents can be reported in aggregate annually. This satisfies public transparency without compromising safety reporting culture or individual privacy.

6. Other feedback relevant to this resource: The final Policy should require a designated, qualified Biological Safety Officer (BSO) for all institutions conducting biohazard research across all risk levels (RG1–RG4 / BSL-1–BSL-4), rather than limiting mandatory BSOs strictly to BSL-3/BSL-4 or GDMO work. To close "title-only" loopholes where under-qualified staff are assigned BSO duties, NIH implementation guidance must define explicit minimum professional qualifications or offer a formal waiver process for certain qualifying institutions. Given the national shortage of qualified biosafety professionals, the proposed 6-month effective date is impractical for recruiting staff while establishing new incident-reporting and public-posting workflows.

In addition, NIH should extend the implementation timeline to at least 12–18 months while providing training resources, guidance templates, and implementation grants to help institutions build compliant infrastructure.

Thank you for the opportunity to provide our comments.

193. George Mason University

I am responding: On behalf of an organization

Name: Ericka Pearce, IBC Contact and Biosafety Officer on behalf of the George Mason University IBC

Name of Organization: George Mason University

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): George Mason University, (GMU)

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Public Posting of Incident Reports and Near-Miss Reporting

George Mason University's Institutional Biosafety Committee supports NIH's goal of increasing transparency and modernizing biosafety data collection. However, the requirement to publicly post incident reports represent a significant expansion beyond the current NIH Guidelines and raises concerns related to confidentiality, security-sensitive information, privacy, and the potential impact on institutional reporting culture.

Public Reporting: NIH should clarify expectations regarding redaction of personally identifiable information, proprietary research information, security-sensitive details, and information that could inadvertently identify students and laboratory personnel. Publicly posted reports should include sufficient contextual information regarding risk assessment, corrective actions, and outcomes to reduce the potential for misinterpretation. The value of incident reporting lies not in public attribution of individual events, but in the ability to identify trends, share lessons learned, and strengthen prevention efforts across the research enterprise.

Operational Impact: The potential for public disclosure may discourage timely self-reporting, voluntary disclosure, and open discussion of incidents and lessons learned. The NIH's OLAW reporting framework demonstrates that effective oversight can focus on institutional response, corrective actions, and program improvement rather than public identification of individuals or institutions. A perceived risk of public exposure could have a chilling effect on reporting culture and reduce participation in voluntary reporting programs. Many incidents covered by the draft policy may already be reportable through existing federal mechanisms, including Federal Select Agent Program reporting requirements and CDC or USDA APHIS permit conditions. NIH should seek to leverage existing reporting pathways whenever possible to minimize duplicative reporting and associated administrative burden while still meeting biosafety and oversight objectives.

Recommendation: NIH should further clarify public posting requirements, establish standardized redaction practices, permit reliance on existing federal reporting mechanisms where appropriate. NIH should also consider a tiered reporting framework based on biosafety risk or public health significance that promotes transparency while preserving strong reporting cultures, protecting sensitive information, and minimizing duplicative reporting requirements.

Additionally, rather than requiring publication of institution-specific incident reports and responses, NIH should consider an anonymized reporting model like the Federal Select Agent Program Annual Report Publications by Federal Select Agent Program | Federal Select Agent Program. Aggregated analyses of key data would provide significant value to both the biosafety and research communities while reducing concerns related to privacy, security, institutional reputation, and potential disincentives to self-reporting. Importantly, data are most meaningful when presented with appropriate context. Isolated incident reports may be prone to misinterpretation and do not necessarily reflect actual risk or compliance performance. Deidentified, aggregated reporting would allow stakeholders to identify trends, understand common challenges, and evaluate the effectiveness of corrective actions. Such an approach would modernize the current OSP reporting framework by providing actionable information to biosafety professionals and IBCs.

Near-Miss Reporting and NBDSAC: We support the development of a national biosafety data repository that captures lessons learned from laboratory-acquired infections, biological exposures, seroconversions, containment failures, and other significant biosafety events. Such a resource has the potential to strengthen biosafety programs nationwide.

However, the draft provides limited information regarding the National Biosafety Data and Safety Analysis Center (NBDSAC), including how data will be analyzed, protected, shared, and translated into actionable recommendations. Investigators may be reluctant to participate if the governance, confidentiality protections, expected outputs, and practical value of the system are not clearly defined. Near-miss reporting systems are most effective when focused on organizational learning and continuous improvement rather than public attribution.

Recommendation: NIH should provide additional detail regarding NBDSAC governance, confidentiality protections, data use, expected outputs, and interaction with existing federal reporting systems. NIH should also describe how findings will be communicated back to institutions and how collected data will be translated into practical guidance, benchmarks, and lessons learned that can improve biosafety and IBC programs nationwide.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

194. Barbara Johnson

I am responding: On behalf of myself

Name: Barbara Johnson

Name of Organization: Barbara Johnson + Associates, LLC

Type of Organization: Other

Type of Organization - Other: Consulting

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosafety and biorisk management for biomedical research and advanced therapeutic platforms

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The following clarifications would help ensure the policy's scope is comprehensive and consistently applied:
• Clarify whether oligonucleotides, cells, and toxins are intended to fall within the definition of biological agent.
• Broaden or clarify the definition of toxin, which currently appears limited to peptides and proteins and does not clearly address synthetic toxins.
• Clarify whether mycotoxins fall within the policy's definition of "toxin" and are considered biohazards under the policy.
• Include animal containment level (ACL) laboratories within the definition of laboratory research, particularly because the policy's scope now encompasses gene drive research.
• Add a definition for self-aggregating protein.
• Define "organism" and clarify its boundaries relative to cells, viruses, biological agents, synthetic or minimal-cell systems, multicellular models, animals, and other engineered biological systems, with representative examples and exclusions relevant to biomedical laboratory research.
• Clarify whether a lipid nanoparticle (LNP)-encapsulated ribonucleic acid (RNA) product is independently within scope before cellular uptake and whether oversight is triggered by handling the formulated product, delivery into cells or research animals, the resulting transiently modified cells, or a combination of these circumstances.
• Address non-viral and non-integrating RNA modalities explicitly, including conventional messenger RNA (mRNA), self-amplifying RNA, circular RNA, naked RNA, and RNA delivered by lipid nanoparticles or other non-viral delivery systems.
• Provide phase-specific examples identifying when LNP-RNA research enters and exits policy scope across RNA synthesis or purification, formulation or handling, in vitro cellular exposure, animal administration, and administration to human research participants, and clarify whether Institutional

Biosafety Committee (IBC) oversight attaches to the material, the activity, the modified cell, or the full protocol.
• Provide risk-assessment criteria for these modalities, including delivery efficiency, biodistribution or cell targeting, persistence, replication competence, integration potential, encoded product, dose or scale, route of exposure, and the potential consequences of unintended cellular uptake, so oversight is calibrated to actual biological risk.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: NIH should clarify how synthetic nucleic acid molecules should be evaluated within the Risk Group framework, including whether they should be assigned a Risk Group or evaluated using separate risk-based criteria. NIH should also identify the characteristics or conditions—such as delivery method, persistence, replication or integration potential, encoded product, concentration or scale, and potential for unintended cellular uptake—that warrant additional control measures for synthetic nucleic acid molecules.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Before establishing mechanisms for voluntary compliance, NIH should clarify the policy's applicability to research supported by other federal agencies. The policy should distinguish between institutions subject to the policy because they receive NIH funding and research funded solely by another government agency. NIH should also clarify whether other agencies are expected to adopt or incorporate the policy into their award terms and how the policy interfaces with government-wide or agency-specific biosafety and biosecurity requirements. In addition, NIH should clarify whether and how the policy applies to NIH-supported research conducted outside the United States, including work performed by foreign recipients, research sites, collaborators, contractors, or other foreign components. NIH should address how institutions should comply when policy requirements differ from local laws, national biosafety oversight systems, privacy requirements, public-disclosure obligations, or IBC composition requirements. For institutions participating voluntarily, NIH should establish reporting timelines that allow sufficient time for required legal, confidentiality, and proprietary-information review before detailed incident information is submitted.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: General Comments on the Draft Policy and Templates
• The 24-hour reporting requirement may be difficult to meet because BSOs are not always notified of incidents within that timeframe.
• The policy should clarify what information must be submitted within the initial 24-hour period and whether the requirement applies to all reportable incidents or only those meeting a defined severity threshold.
Incident Reporting Template
• The template should include options for chronic exposures and laboratory-acquired infections (LAIs).
• The incident reporting template should request the amount or concentration of the biohazardous material or organisms involved in the incident.
• The incident narrative should ask whether secondary transmission to another person or animal host occurred outside the laboratory.
Meeting Minutes Template
• The Meeting Time field should include the applicable time zone.

• Align the Meeting Minutes Template with the policy's mandatory IBC membership and quorum requirements. For example, the template describes participation by at least one non-affiliated member as a recommendation, while the policy requires at least two non-affiliated members.
• Clarify how voting members make decisions, including whether approval is based on a majority vote, and add corresponding voting-decision details to the Meeting Minutes Template.

6. Other feedback relevant to this resource: Additional guidance would be beneficial in the following areas:
• Clarify whether institutions are required to appoint an Authorized Organizational Representative (AOR) and specify the qualifications or selection criteria for this role.
• The policy should clarify whether IBC community members must reside within a specified distance of the site served by the IBC.
• The policy should clarify whether a BSO may also serve as the IBC Chair.
• Ad hoc consultants should not fill designated community-member positions on an IBC. Compensating an individual serving in a community-member role could create an actual or perceived conflict of interest.
• Provide instructions or a supporting resource describing how institutions may petition NIH to assign a Risk Group to a new or emerging agent not addressed in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).
• Clarify the NIH office or body to which reportable incidents must be submitted and provide a single, clearly identified reporting pathway.
• Clarify whether theft of biohazardous material is a reportable incident and whether biosecurity incidents are within the scope of the policy.

Additional Request for Clarification:
Section III-C should distinguish voluntary submissions from required incident reports. Incidents involving an environmental release or a laboratory-acquired infection appear to require reporting to NIH and therefore should not be characterized as voluntary submissions.
In Section V-E, present mitigation measures in an order consistent with the recognized hierarchy of controls: elimination or substitution, where feasible; biological containment based on agent or organism design; physical or engineering controls, including facility design and primary barriers; administrative controls, including practices, procedures, and training; and safety equipment and personal protective equipment.
Before implementation, NIH should provide stakeholders an opportunity to review and comment on the next draft of the policy, particularly if substantive revisions are made in response to the current public comment period. An additional review period would help identify implementation challenges and clarify requirements before the policy becomes effective.

195. Joan E. Nichols

I am responding: On behalf of myself

Name: Joan E. Nichols

Name of Organization: Houston Methodist Research Institute

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: A large gap in IBC oversight relates to use of RNA and DNA proteins for vaccine development. I highly recommend that clear guidance be provided by NIH to require that institutional IBCs review all protocols for mRNA, DNA, and protein expression of all select agents and Risk Group 3 and 4 agents. Although these materials might not threaten physical safety, they carry inherent biosecurity risks.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

196. Harjinder Sardar

I am responding: On behalf of myself

Name: Harjinder Sardar

Name of Organization: Oregon Health and Science University

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): OHSU

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Define the boundary of the policy
The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.
Use internally consistent terminology
The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.
Clarify plant and animal coverage
CSHEMA | Public Comment
The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.
Calibrate toxin and protein scope to meaningful risk
The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins

without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other
self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition.
NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.
Separate scientific definitions from policy applicability
“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs
at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.
Clarify policy application on existing IBC approvals
NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.
As written, “may be contaminated” could be interpreted to include virtually any primary human or animal cells (including any research involving NHP cells or tissues) for which the infectious-agent status of the source has not been comprehensively established.
NIH should define “adventitious agent,” establish a risk-based threshold for determining when contamination is reasonably anticipated, and clarify whether donor screening, testing, source information, or other documentation can establish that primary cells do not fall within this category. The Policy should also clarify its application to commercially obtained cells, repository specimens, patient-derived cells, and primary animal cells and provide examples of included and excluded materials. A merely theoretical possibility of contamination should not independently trigger IBC oversight; the definition should be tied to a known or reasonably anticipated potential hazard to human health. Clear criteria are necessary to avoid additional administrative burden by unnecessarily expanding IBC oversight beyond research presenting a meaningful biosafety risk.

The Policy does not provide sufficiently objective criteria for determining when a cell line qualifies as well-characterized, creating the potential for inconsistent interpretations among investigators, biosafety professionals, and IBCs. NIH should specify what level of information regarding identity, provenance, biological characteristics, and adventitious-agent testing is necessary; whether established commercially available or widely used cell lines may be presumed to satisfy the definition; and how primary, immortalized, genetically modified, and patient-derived cells should be treated. NIH should also provide examples of included and excluded cell lines. Because this determination may affect the scope and level of institutional oversight, a clear, risk-based definition is necessary to ensure consistent implementation and avoid additional administrative burden by unnecessary review of research that does not present a meaningful biosafety risk.

IBC review is appropriate for the review of research involving prions or biospecimens identified to be from a person or animal known to have a prion-based disease. However, the term self-aggregating is not

sufficiently defined to permit institutions or investigators to determine consistently if every protein that happens to aggregate or contributes to an aggregation-associated human disease, such as ALS, is also covered.

Protein aggregation alone does not necessarily establish a meaningful biosafety hazard. NIH should clarify whether "other self-aggregating proteins" is intended to encompass proteins with prion-like, seeding, propagation, transmissibility, pathogenic, or other specified hazard characteristics rather than any protein capable of aggregation. The definition should identify objective criteria and provide examples of both covered and excluded materials.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported "in full" at the

next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway

is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report

to the IBC, with records retained for audit. The full committee's role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently

routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Continued utility of Risk Groups: Retain Risk Groups as a starting point
Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.
Distinguish genetic engineering from other forms of change
The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.
Avoid rigid containment rules that conflict with risk assessment
A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment
and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language
that could apply to any construct containing any listed segment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Align accountability with authority
The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.
Provide procedures for managing overlapping federal policies
The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.
Assign institutional responsibilities appropriately
The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.
Clarify governance requirements
A member who is recused because of a conflict should not count toward the quorum needed for action on
that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations
for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have

difficulty recruiting unaffiliated members.
Recalibrate public posting
Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.
Define redaction and timing rules
If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions
necessary for the protection of proprietary and security-sensitive information. The NIH must also establish
a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.
Map retention requirements to record types
The final policy should include a record-retention table for protocols, risk assessments, delegated reviews,
training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and
any superseding award or legal requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It is recommended that NIH revise the approach to public posting of incidents so that detailed incident reports are submitted to NIH but are not routinely required to be posted publicly in their entirety. Alternatively, NIH could provide a template for public posting of standardized, de-identified high level summary information of incidents that might include root-cause categories and corrective actions. NIH could separately require disclosure of additional information when a particular incident presents a compelling public health or safety interest.
This approach balances transparency objectives with the equally important need to preserve a just, non-punitive reporting culture in which researchers and staff are encouraged to report incidents, near misses, and potential safety concerns promptly and completely. It also provides protections for researchers that are increasingly threatened or harassed due to the tools or subject matter of their research.
Importantly, NIH would receive the information necessary to evaluate significant incidents, institutional responses, and compliance. The distinction would therefore be between information necessary for regulatory oversight and information necessary for public transparency, rather than assuming that the same level of detail is needed for both purposes.

6. Other feedback relevant to this resource: The timeline for institutional implementation and compliance with the revised policy should be at least a year after the publishing of the final rule instead of 6 months.
A six-month implementation period is insufficient given the breadth, complexity, and institutional

impact. Revising electronic systems to accommodate the new regulations is a significant challenge that will likely prevent many institutions' ability to meet this timeline. Additionally, updating policies and procedures and ensuring that researchers have the training they need to understand the new requirements, including newly covered areas of research, will require additional time. The time required to identify newly covered research is one reason why it is critical for entities to be held to realistic and achievable implementation timelines.

NIH should provide a detailed description of the required elements of an institutional assurance and publish accompanying implementation guidance before policy adoption, including model assurance language, implementation templates, and sufficient lead time for institutions to develop. Administrative burden should be kept in mind in considering required elements.

197. Alexandra Elliott

I am responding: On behalf of myself

Name: Alexandra Elliott

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Currently, sections III-E-3-a and III-F of the NIH Guidelines include specific materials involving recombinant or synthetic nucleic acids as well as transgenic rodents that are exempt from the Guidelines. In the new policy, it sounds like these projects would now fall under section IV-3 and would now need an IBC review. Is this the correct interpretation? If so, I would suggest that these low risk projects continue to be exempt in the new policy since they pose little risk to the people working with them. There have been no laboratory acquired infections documented from exposures to materials or transgenic animals listed as exempt in the current NIH Guidelines.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): One of the most positive aspects of the new NIH Biosafety Policy is the alignment with the BMBL. The focus on a thorough risk assessment in order to assign a containment level for projects is another welcome addition in the new policy.

3. Continued utility of Risk Groups: Section IV-1 in the draft policy requires both NIH and IBC approval and lists the following as falling under this category:
Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL.

In the draft policy, chimera viruses are defined as "novel agents", which would put them in the highest risk category. Chimera viruses most commonly consist of a non-hazardous virus with different pieces of a hazardous virus attached to it, in order to test for antibody production. Will every chimera moving forward need to be reviewed by both the NIH and IBC? Or will common chimeras be able to be included in a section IV-2 review (ex. VSV based chimeras)? Could NIH develop a definition of chimera virus that more clearly delineates the level of risk and review?

The policy states that un-modified RG1 organisms are exempt from the policy. Is this defined as RG1 listed in the BMBL, meaning that organisms classified as RG1 in other publications would still fall under this policy if they are not specifically listed as RG1 in the BMBL? As written, it seems as though the policy

treats non-hazardous gut microbiota, such as found in in over the counter pro-biotic supplements, as higher risk organisms because they are not specifically listed in the BMBL. Could NIH clarify how non-hazardous bacteria should be categorized if the species does not have an affirmative RG1 classification? Otherwise, there could be an unintended consequence where NIH program staff may experience increased administrative burdens of updating a high volume of RG1 classifications for research to proceed.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: There are concerns of unintended consequences regarding the public posting of biohazard incident reports. Currently, the incident reporting and review process receives significant buy in and participation from investigators as it is seen as a positive process to learn from incidents and improve safety systems and processes. Because of this positive attitude regarding incident investigations, PIs readily report biosafety incidents. I am concerned that posting the incident reports on a public website and requiring the PI name and funding sources could discourage how forthcoming PIs and their laboratory personnel are about reporting incidents. The PI name and funding information does not add to the incident analysis, which helps determine the cause of the incident and helps to prevent similar incidents from occurring in the future. Additionally, the PI name and funding information is not necessary for demonstrating public transparency to the local community. Incident reports could be publicly posted without this information to demonstrate transparency.

A better definition of a “significant” incident is needed to classify incidents that occur.

6. Other feedback relevant to this resource: Extending the implementation timeline from 6 months to 12 months for newly in scope research projects would help smooth out the administrative labor needs for both the initial review processes and re-review every three years. Grandfathering existing IBC approvals for projects would also help mitigate administrative burdens and then have those projects comply with the new requirements for the next review cycle after the policy is finalized.

198. ABSA International

I am responding: On behalf of an organization

Name: Antony Schwartz

Name of Organization: ABSA International

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): All areas of biomedical research affected by the proposed NIH Policy. ABSA International, The Association for Biosafety and Biosecurity, represents professionals whose biosafety and biosecurity responsibilities span these research domains.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see the attached document for detailed comments from ABSA International.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see the attached document for detailed comments from ABSA International.

3. Continued utility of Risk Groups: Please see the attached document for detailed comments from ABSA International.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comments at this time.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see the attached document for detailed comments from ABSA International.

6. Other feedback relevant to this resource: Please see the attached document for detailed comments from ABSA International.

Uploaded File: ABSA-NIH-Biosafety-Policy-Comments-Final-14Oct2026-LETTERHEAD.pdf

Description: ABSA International's comments on the draft NIH Biosafety Policy, including recommendations for clear, risk-based oversight, proportionate incident reporting, meaningful public transparency, and protection of sensitive information.

ABSA International — The Association for Biosafety and Biosecurity

Organization:	ABSA International 1200 Allanson Road, Mundelein, IL 60060 Phone: (866) 425-1365 | Email: info@absa.org | Web: www.absa.org
Date:	October 19, 2026
To:	Office of Science Policy National Institutes of Health 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892
Submission Portal:	Submitted via NIH OSP Electronic Comment Portal
Subject / Notice:	Formal Public Comments and Recommendations on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice Number: NOT-OD-26-112)

ABSA International, the Association for Biosafety and Biosecurity, is a nonprofit professional association representing biosafety and biosecurity professionals in the United States and internationally. Our membership spans academic and research institutions, government laboratories, biotechnology companies, healthcare organizations, public health agencies, and consulting practices. Members bring scientific, technical, operational, and regulatory expertise across diverse biological research and laboratory settings.

ABSA's comments reflect the practical experience of professionals responsible for translating biosafety policy into daily practice. Our members conduct risk assessments, support Institutional Biosafety Committees (IBCs), develop training and containment practices, investigate incidents, and advise institutions on compliance. They understand how policy requirements affect laboratory safety, reporting culture, institutional resources, and the conduct of research.

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public

confidence in NIH-supported science. ABSA supports NIH's efforts to strengthen biosafety oversight. We offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

***Topic to Address**: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:

    a. the nature and stability of the genomic modification;

    b. whether the modification is heritable and the potential for transmission through breeding;

    c. effects on animal health, phenotype, host range, susceptibility, or disease;

    d. potential entry into breeding or food-production systems;

    e. potential environmental release or interaction with non-research animal populations;

    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and

    g. applicable federal, state, or other regulatory oversight.

2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

  Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

ABSA International believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, ABSA International requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, ABSA International welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. ABSA International does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. ABSA International recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, ABSA International recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with ABSA's earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. ABSA International recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, ABSA International kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. ABSA International encourages NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While ABSA supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: ABSA recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

199. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): all

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Create a clear precedence rule
Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

200. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

201. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Remove mandatory review of routine minimal-risk activities
Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

202. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

203. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

204. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

205. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definition of "biological agent" is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

206. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

207. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other
self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition.
NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

208. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: "Biomedical research" should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

209. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

210. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Risk Groups remain useful for hazard communication and initial characterization, but they should not
independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

211. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: The proposed definition of genetic modification includes passaging, reassortment, and chemical or
radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

212. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse,
ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment
and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language
that could apply to any construct containing any listed segment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

213. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and
IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

214. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The draft says research also under another federal agency's regulation or purview "may proceed under
the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

215. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The PI can ensure proper use of equipment and report deficiencies, but may not control building
ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

216. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): A member who is recused because of a conflict should not count toward the quorum needed for action on
that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations
for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

217. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Public posting of detailed IBC minutes and all incident reports could expose proprietary research details,
personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

218. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions
necessary for the protection of proprietary and security-sensitive information. The NIH must also establish
a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

219. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The final policy should include a record-retention table for protocols, risk assessments, delegated reviews,
training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and
any superseding award or legal requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

220. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft should define “incident,” “basic first aid,” “agent-specific treatment,” “potential exposure,” “compliance violation,” and “minor spill.” The policy should clarify whether precautionary post exposure prophylactic treatment is considered “agent-specific treatment”. It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

6. Other feedback relevant to this resource: N/A

221. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

6. Other feedback relevant to this resource: N/A

222. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The proposed six-month effective date is not realistic for institutions that must inventory newly covered
research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

223. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The proposed six-month effective date is not realistic for institutions that must inventory newly covered
research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

224. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Needed resources include a Biosafety Assurance template; model policies; decision trees;
risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

225. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess
financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

226. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Officer - why isn't this an option for a draft on a BIOSAFETY Policy?

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Define the boundary of the policy: The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.
2. Use internally consistent terminology: The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. NIH should also define GDMO and consistently use the term throughout the policy.
3. Clarify plant and animal coverage: The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.
4. Calibrate toxin and protein scope to meaningful risk: The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.
5. Separate scientific definitions from policy applicability: “Biomedical research” should be defined by

the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.
6. Clarify policy application on existing IBC approvals: NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 1. Create a clear precedence rule: Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.
2. Ensure delegated review actually streamlines oversight: Delegated review is a welcome modernization, but requiring every approval to be reported "in full" at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee's role after delegated approval should also be defined.
3. Remove mandatory review of routine minimal-risk activities: Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not require IBC review when they present minimal biosafety risk. Requiring this review seriously undermines the credibility of this policy.
4. Limit federal review to clearly defined circumstances: Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.
5. Make NIH precedents reusable: NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Continued utility of Risk Groups: 1. The four groups address the risk to both the laboratory worker and the community and correlate with, but do not equate to, Biosafety Levels (p12 - BMBL 6th Ed).: Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

2. Distinguish genetic engineering from other forms of change: The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.
3. Avoid rigid containment rules that conflict with risk assessment: A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): 1. Align accountability with authority: The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.
2. Provide procedures for managing overlapping federal policies: The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required and what records the IBC is required to receive, review, or retain when concurrent IBC is not required.
3. Assign institutional responsibilities appropriately: The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures. The policy should define the role of BSO and the requirement for being a BSO.
4. Clarify governance requirements: NIH should specify the expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.
5. Recalibrate public posting: Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.
6. Define redaction and timing rules: If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response."

Institutions should not be held to a posting deadline that depends on an open-ended federal review.
7. Map retention requirements to record types: The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1. Resolve overlapping and undefined categories
The draft should define “incident,” “basic first aid,” “agent-specific treatment,” “potential exposure,” “compliance violation,” and “minor spill.” The policy should clarify whether precautionary post exposure prophylactic treatment is considered “agent-specific treatment”. It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.
2. Keep reporting of lower-risk events within local IBC purview: NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.
3. Use aggregate public reporting
The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency.

6. Other feedback relevant to this resource: 1. Provide a minimum 36-month phased implementation period: The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 36 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.
2. Pilot the policy and templates: NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.
3. Develop implementation resources: Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

4. Address the cost of compliance: The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.
5. Allow flexible institutional models: The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

227. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid
arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities
while preserving meaningful independent input.

228. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: the following should be included in the final text or in binding implementation guidance published with the final text:

● Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
● Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
● Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
● Define when a prior NIH containment determination may be used by another institution without a new
petition.
● Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
● Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
● Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events,

minor spills, and compliance violations that do not present a meaningful safety risk.
● Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

229. University of Virginia

I am responding: On behalf of an organization

Name:

Name of Organization: University of Virginia

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

230. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Coverage and decision rules
The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration: Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration: Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Policy reference: Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration: Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration: Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident thresholds: investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration: Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration: Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration: Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

6. Other feedback relevant to this resource: (1) Public disclosure and record retention:
The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public

disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

(2) As biosafety compliance faces increasing scrutiny, it would be beneficial for the institution to provide financial support for these types of biosafety oversight activities.

(3) Assurance submission approval and renewal
A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration: Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration: Specify and define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration: Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

231. University of Texas Medical Branch

I am responding: On behalf of myself

Name:

Name of Organization: University of Texas Medical Branch

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am an Associate Professor at the University of Texas Medical Branch. I have worked in the field of infectious diseases, particularly on important human pathogens, including viruses requiring biosafety containment levels ranging from BSL-1 to BSL-3. I support replacing the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) with a risk-based biosafety oversight framework. I offer these comments to help the NIH develop clear, proportionate, and practical requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The significant concerns raised in these comments, as well as by the broader scientific community, demonstrate that the draft Policy cannot be implemented in its current form. We respectfully request that the NIH revise the Policy and publish additional drafts for public comment before issuing a final version. While we fully support the NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy could hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and undermine the collaborative relationship among researchers, regulators, and the biosafety compliance community.

1) The stated intention of this policy proposal is to expand the scope of the NIH Guidelines while removing red tape for low-risk research. The goal of removing red tape for low-risk research within this Policy has not succeeded. The Draft Policy includes within its scope multiple categories of research that are currently Exempt in the NIH Guidelines. For example, research with certain transgenic rodents and certain recombinant work with non-pathogenic E. coli; the NIH Director has already determined that these experiments are of such low risk that they were actively designated as Exempt, yet this Policy considers them of high enough risk to require IBC approval. The Policy does not provide reasoning for this change in the risk assessment.

2) A meaningful administrative burden with the NIH Guidelines is the pathway through which NIH OSP will assign a biocontainment level for research with an agent that does not have an assigned RG within

Appendix B. This issue could be less burdensome if NIH OSP had been granted authority within the Guidelines to assign a risk group to agents that do not have risk groups.
3) The current approval pathway is limited to the specific PI at a specific entity. Therefore, other PIs at the same entity are similarly required to obtain a biocontainment level from NIH OSP for the same agent.
4) The Scope of the Policy states "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." This statement must be clarified. We appreciate that the Policy seeks to avoid duplicative oversight from multiple federal agencies. However, the statement itself is unclear regarding the oversight, approvals, and clearances that are mentioned.
a. If a researcher is registered to work with wildtype Nipah virus (RG4, therefore falling under Section IV-2) with the Federal Select Agent Program (FSAP), do they not need to obtain IBC approval for the same work?
b. If a researcher is registered to generate chimeras of paramyxoviruses within a Nipah virus backbone (a novel agent by the current definition, therefore falling under Section IV-1) with FSAP, do they need to obtain NIH and IBC approval for the same work?
c. If an incident occurs in a BSL3 or BSL4 that involves a Select Agent for which the researcher is registered with FSAP, does the incident get reported to NIH and posted on a public facing website?

5) Effective Date. The Policy states that the effective date will be 6 months from publication of the final Policy. This is a very short timeline to implement a Policy with such significant expansions in scope. Implementation of this Policy will require that IBCs ask for more resources from their institutions, obtain those resources, communicate with stakeholders, develop new training, implement training for IBC members and researchers, obtain new software or update software, and make significant choices in how to implement each part of the Policy. Six months is not nearly sufficient, and all entities will struggle. This is further complicated by the need to provide a written Biosafety Assurance that has been approved by NIH in order to perform any research after the effective date. Will NIH have the FTEs to review and approve hundreds of Biosafety Assurances that will be submitted within that effective date?
6) The Policy uses terms and words but does not define them. The failure to define these words will lead to ambiguity in the interpretation and implementation of the Policy, leading to unintentional noncompliance. Further, some of these words did not have definitions in the NIH Guidelines and therefore this is a good opportunity to rectify this issue. These include:
a. Adventitious agent, organism, transgenic, GDMO, incident, release, potential risk to human health, peptide, shedding. Organism is inconsistently used within the Policy and is not an easily defined word. Replace "organism" with more appropriate and easily definable terms throughout the Policy. Specify bacteria, fungi, archaea, protists, viruses, or animals as needed. If there is a concern about a biological agent that doesn't fall within those terms, be clear about that (e.g., a biological agent created through synthetic biology that cannot be readily categorized).
b. The Policy omits a review workflow for biological agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL yet cannot reasonably fall within the definition of "emerging, novel, or zoonotic agents". This is a crippling issue for agents that are currently handled at BSL1 or BSL2, though is also an issue for agents handled at BSL3 and BSL4. Theoretically, these could fall within Section IV-1 (research that requires NIH and IBC approval before initiation). However, the administrative burden on NIH to adequately review this work in a timely manner would be significant (even ignoring the administrative burden on researchers and IBCs to review

this work). Additionally, much of this research cannot reasonably fall under the category of “higher risk research”, when even research involving RG3 or RG4 wild-type biological agents requires only IBC review in the Policy.
For example, human metapneumovirus, non-polio enteroviruses, human parainfluenza virus 5 (Orthorubulavirus mammalis), and Sendai virus (Respirovirus muris) are not emerging, novel, or zoonotic agents. Yet they lack a risk group in the NIH Guidelines and are not mentioned in the BMBL. Will NIH review be required for research with these agents for every entity and researcher that falls in scope of the Policy? If so, how many FTEs will NIH be hiring to accomplish timely reviews?
How will human or animal microbiota be treated in this review workflow? Will research with every member of Bacteroides, Bifidobacterium, Akkermansia, Ruminococcus, Prevotella, and Anaerococcus require NIH review? If so, will a researcher even be able to collect a human or animal sample without being in noncompliance with the Policy?
c. The Policy does not define who has the authority to designate the risk group of an agent. This is of particular importance with RG1 biological agents, since the Policy explicitly states that wild-type RG1 biological agents are outside the scope of the Policy. If the local IBC will have the authority to designate the risk group of an agent, that needs to be stated in the Policy. If the NIH will have the authority to designate the risk group of an agent, that needs to be stated in the Policy. In addition, NIH must publish and regularly update the list of biological agents that it designates at different RGs.

7) Responsibilities of the Institution (Section III-A), related to records retention. The Policy states “The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states “the recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report.” (emphasis added). The Policy assumes that all IBC records are for projects that are federally funded. The Policy has failed to consider projects that are not federally funded and therefore will never submit a final financial report. As written, such IBC records may never be disposed of, which is either an oversight or regulatory overreach. This language must be changed to account for IBC records related to non-federally funded projects.

8) The Policy states “Approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required.” The Policy fails to describe how biosafety or biosecurity is increased by limiting research approvals to three years. Researchers continue projects over years and decades, and these projects rarely include changes that significantly increase the risk assessment. Requiring a specific time frame for approvals is overly burdensome and regulatory overreach. Requiring such a short approval time will greatly increase the administrative burden of the IBC and the researcher for little to no increase in biosafety. We recommend that this statement be removed from the Policy. If the statement cannot be removed from the Policy, we recommend that the Policy explicitly permit grandfathering of previously approved IBC protocols that have approval periods of greater than three years.

9) Responsibilities of the IBC (Section III-B), incident reporting. The Policy does not define “incident” or “release”. We recommend the following definitions:
Incident: A confirmed theft, loss, or release (such as an occupational exposure or a release outside the

defined biocontainment barriers) of biological material under the scope of the Policy.
Release (Loss of containment or occupational exposure): Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
The Policy does not define "improper disposition" and throughout this section relies on ambiguous phrases such as "any incident", "loss of containment", "significant problems", and "minor spills … generally do not need to be reported". Terms like "first aid" and "medical treatment" should be aligned explicitly with OSHA standards.

10) Responsibilities of the NIH (Section III-D)
The Policy does not state which person or office within NIH will be responsible for these items. In comparison, the NIH Guidelines clearly delineated the responsibilities of the NIH Director and the responsibilities of the NIH Office of Science Policy. Entities can reasonably expect that the response times for the NIH Director and for NIH OSP will be significantly different. Further, NIH OSP is staffed with many subject matter experts, while the NIH Director can never be an SME for every aspect of biomedical science. Therefore, the Policy must clearly state who will be responsible for these duties. We recommend that the Policy clearly state which person or office is responsible for the duties described in this section.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 1) In general, the tiered oversight is appreciated. The IACUC-style review that specifically permits delegate approval will be a helpful decrease to time commitments from the full IBC for review of lower risk research. The Policy has replaced two previous categories of review, those requiring NIH Director approval (III-A) and those requiring NIH OSP approval (III-B), with a singular category that requires NIH approval. The Policy does not describe which person or office within NIH will be performing the review and approval of research within Section IV-1. This must be clearly stated in the Policy within the Responsibilities of NIH (III-D).

2) General Definitions: Emerging agent or organism. The Policy does not state who determines that an agent is an emerging agent. Does the local IBC decide what qualifies as an emerging agent? If not the local IBC, we recommend that NIH develop rapid dissemination notices that are sent to all entities identify emerging agents so that entities can avoid noncompliance.
The Policy does not describe how an agent or organism goes from being an emerging agent to a non-emerging agent. Will an agent be "emerging" until the first time NIH has reviewed it under Section IV-1? Until it has been assigned a risk group? Until it has appeared in the next edition of the BMBL? Does the definition of an emerging agent include a well characterized agent that exhibits a change in pathogenicity or transmission? If this Policy existed at the time, would the recent outbreaks of Zika virus, mpox virus, and Andes virus qualify as "emerging"? Would the label of emerging apply to the agent, or merely to the specific strain of the biological agent? If considered now (October 2026), which agents would qualify as "emerging"? Highly pathogenic avian influenza virus H5N1? SARS-CoV-2?

3) General Definitions: Genetic Modification. This definition is so expansive that it causes internal contradictions within the Policy. The definition uses the undefined word "organisms", which is unhelpful. As written, this causes the Policy to confusingly regulate research conducted with genetically modified organisms (Section IV-2) differently from transgenic organisms (Section IV-3) but does not define the difference between the two. Replace the word organism with the biological agent(s) that are intended to

be within scope of the Policy.
Can be transcribed or translated: as written, this will include expression from an RNA vaccine that is administered to an animal or transfected into a cell line. The Policy does not describe how including this as a genetic modification addresses a biosafety concern. The introduction … of stable alterations into the genome by passaging, reassortment, chemical or radiological means: as written, the definition includes unintentional alterations into the genome, such that researchers will become noncompliant with the Policy almost immediately.
Passaging any virus in tissue culture will result in unintentional alterations into the genome. Cancer research includes work with antineoplastic drugs that would fall within scope of this definition. We recommend that this definition be re-written to be limited to intentional stable modifications.

4) General Definitions: Toxin. The definition of toxin could be greatly improved. For example, ISO35001 uses “substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants. This includes substances and materials, natural or as a result of biotechnology, that may contain toxins, any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance.” The definition should not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (e.g., sensitizers).
Later in the Policy, when defining the Category of research, would be the appropriate time to limit the scope of which toxins fall under the Policy (e.g., Research with protein or peptide toxins not on the Select Agent list and with an LD50 of less than 100 micrograms per kg body weight.)

5) Section IV-1 (Research that Requires NIH and IBC Approval Before Initiation): Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL.
Emerging and zoonotic agents: For those whose research focuses on the identification of new biological agents, the Policy offers no regulatory path to work with these agents. Once identified as an emerging or zoonotic agent with no risk group or biosafety level recommended in the BMBL, the research must be approved by NIH. However, without the ability to work with the agent, the researcher cannot generate the data required for NIH to conduct the risk assessment. Without the ability to perform this research, US researchers will stop performing this work. It will then fall to international researchers to spearhead this work, leaving US researchers lagging behind. We recommend that a clear approval pathway is described in the Policy to allow researchers to generate the data required for a risk assessment. This would best be performed by the local IBC.

6) Novel agents: The definition of novel agents includes chimeras. Many researchers generate chimeras (especially within a family of viruses) to study the basic biology of these agents; in these cases, the representative family member or the parental agents often already have risk groups assigned or biosafety levels recommended. Research with such biological agents does not qualify as “higher risk research” requiring NIH approval; indeed, these experiments currently fall within Section III-D of the NIH Guidelines, clearly demonstrating that for decades NIH has determined that the work can be reviewed by the local IBC and does not require NIH approval. We recommend that research involving chimeric agents generated within the same family (for viruses) or the same genus (for bacteria or fungi), may be reviewed by the IBC. We recommend that research involving chimeric agents where the natural sources

have risk groups assigned and/or biosafety levels recommended, may be reviewed by the IBC.

7) Section IV-2 (Research That Requires IBC Review and Approval Before Initiation). This section states "For initial submissions of research within the scope of the policy, and not otherwise specified in other sections, review and approval must be obtained from the IBC before initiation." Since the Policy includes a regulatory catch-all ("not otherwise specified in other sections"), the Policy must include a section that clearly delineates research that is outside the scope of the Policy. Institutions cannot rely on one-off notes to define research that is outside the scope (e.g., "[Note: Experiments involving RG1 wild-type biological agents are not subject to this Policy]"). Without clear delineation, entities will vary widely between unintentional noncompliance and overly requiring IBC review and approval for work that is outside the scope of the policy.

8) Section IV-2: Research involving RG3 or RG4 wild-type biological agents. We have no objection to including RG3 and RG4 biological agents within scope of the Policy, as our institution already requires that work with these agents be approved by the local IBC.
9) Section IV-2: Research involving genetically modified cells, viruses, or organisms, other than plants (e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs). Policy must be well written and clear; this category is a clear example of policy that is not well written. It is misplaced within the tiers of review; contains terms that are either not defined or badly defined; and conflicts with other categories of research within the Policy. Entities will be uncertain how to comply with this category, leading to chilling effects on the research community, additional administrative burden, and unintentional failures to comply with the Policy. This category is misplaced within the tiers of review. Research with genetically modified cells should be at most within Section IV-3 (delegate review), if not Exempted completely.
The NIH Guidelines has included an exemption for recombinant DNA molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in tissue culture at least since the Federal Register Notice in 1994 (Effective June 24, 1994, Published in Federal Register, July 5, 1994 (59 FR 34472)). The NIH Director has therefore determined that such experiments do not present a significant risk to health or the environment. The Policy does not describe how the inclusion of such research in the Policy will increase biosafety and biosecurity. In addition, while a single researcher registering for this work would not be a significant burden, the total number of registrations will constitute a significant collective administrative burden on the IBC and researchers that is not commensurate with the very low biosafety risk.
10) Genetic modification of cells is of very low biosafety risk (barring some introduction of nucleic acids from certain biological agents, like RG3 or RG4 agents, or that will generate toxins). Such work should be exempt from the Policy. Genetic modification is defined by the Policy, but in such an expansive way that that it is prohibitive to research. As an example: as written, the Policy no longer considers administration of recombinant nucleic acids (e.g., RNA vaccines) in humans to be within scope, compared to the NIH Guidelines, where it is within scope (Section III-C-1). However, the Policy includes "genetic modification" of cells and organisms, which as defined includes introduction of nucleic acid molecules that can be transcribed or translated (e.g., RNA vaccines). The Policy does not describe how it has conducted a risk assessment in which deliberate administration of an RNA vaccine into a human is not within scope, yet transfection of the RNA vaccine into cell culture or administration into an animal is within scope and requires IBC approval.

11) Organism is not defined by the Policy, which makes this category frustrating to understand and will lead to significant unintentional noncompliance. As written, this category appears to include animals, despite the category of “transgenic organisms at BSL1/ABSL1” listed in Section IV-3. The word organisms must be defined by the policy or replaced in this section.

12) Vector is not defined by the Policy, which will lead to significant unintentional noncompliance. Is the intention here to regulate viral vectors (e.g., lentiviral), arthropod disease vectors (e.g., mosquitoes), or something else?

13) Gene drive modified biological agents is not defined and is a confusing term. Biological agents in the Policy are defined as bacteria, viruses, fungi, or parasites, yet gene drive technology requires Mendelian genetics, such that this would be limited to fungi or parasites. The subsequent use of GDMO in this category suggests that gene drive modified biological agents are different from GDMOs, but this delineation is not clear.

14) GDMOs are not defined in the Policy. We recommend that this category be removed from the Policy or extensively re-written, as described below. The definition for Genetic Modification should be re-written to be limited to stable alterations in the genome. Definitions for organism, vector, GDMO and gene drive modified biological agents must be added to the Policy (or removed).
Research with genetically modified risk group 3 and 4 biological agents should be approved by the IBC.
Research with genetically modified risk group 2 biological agents should be approved by IBC delegate.
Research with GMDOs should be approved by the IBC.
Review and approval of research with genetically modified cells should be dependent on the modification, some of which may fall within IBC approval, delegate approval, or be completely exempt from the Policy.
15) Section IV-2: Research with primary cells that may be contaminated by adventitious agents. As noted above, the Policy does not define adventitious agents. Therefore, entities will be uncertain how to comply with this regulation and will rapidly be in noncompliance. If the intention of the Policy is to regulate primary cells that may be contaminated by bloodborne pathogens, there is a significant risk assessment issue: research with samples that may be contaminated requires full IBC review, yet research with known RG2 biological agents requires delegate review.
For clinical samples suspected to contain higher consequence pathogens (Brucella, Herpes B, M. tuberculosis, etc.), the BMBL states that BSL2 practices, containment equipment, and facilities are recommended for routine handing of clinical specimens of human or animal origin. The Policy should harmonize the level of review required for these samples: at most they should require delegate review.
We recommend that this section be removed from the Policy. If it must be regulated by the Policy, “adventitious agent” must be clearly defined within the Policy. If it must be regulated by this Policy, we recommend that this work not require IBC or delegate approval as long as the entity is complying with OSHA Bloodborne Pathogens Standard or its equivalent. If it must be regulated by this Policy, we recommend that it should not fall under the category of requiring IBC approval and should at most be in Section IV-3, where delegated review is permitted.
If the intention of the Policy is to regulate primary cells that may be contaminated by any unknown biohazard (for example field samples), that is not clear and needs to be much more clearly defined.

16) Section IV-2: Research with wild type or genetically modified RG2 biological agents for which lower containment is requested, or research with wild type or genetically modified RG3 or RG4 biological agents that NIH has previously approved to be conducted at lower containment.

The Policy implies that there will be a workflow of (1) an entity submits an initial request for NIH to lower containment involving wild type or genetically modified RG3 or RG4 biological agents, (2) NIH will make a determination on whether that lower containment is appropriate, (3) NIH will be responsible for publishing approved determinations of appropriate lower containment for these agents, (4) subsequently, research involving these agents may be approved by the IBC alone (without NIH approval). This workflow should be expressly stated in the Policy to minimize confusion. This includes a clear statement that once NIH has made the determination and published it, other entities will not be required to obtain NIH approval. This would be in contrast to the current system, where approvals are provided only to the single PI at the single institution.
The method by which NIH will publish these determinations should be described, including the minimum time frame (determinations will be published within 1 month, within 6 months, annually, etc.).

17) The Policy should be clear on how much information will be released together with these determinations. Specifically, whether the information include security sensitive information or unpublished data.

18) Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): Research involving RG2 wild type biological agents.
We have no objection to including RG2 biological agents within scope of the Policy, as our institution already requires that work with these agents be approved by the local IBC. However, we are very concerned that there is not a thorough list of RG2 biological agents and/or biological agents that are recommended to be worked with at BSL2. Will all agents not listed in the BMBL require review by NIH? We recommend that the NIH make a detailed, publicly available list of RG1, RG2, RG3, and RG4 biological agents to supplement the BMBL. Appendix B of the NIH Guidelines should serve as the backbone of this document.
The inclusion of RG1 organisms is an important part of such a list, since they are outside the scope of the Policy, yet the Policy specifically states that “absence of agent specification in the list of RG2-RG4 does not imply automatic or implicit classification as RG1”. If other federal entities (USDA, CDC, etc.) participated in creating a central list that also includes plant or agricultural considerations, that would be greatly appreciated. If NIH cannot make a detailed publicly available list of RG1, RG2, RG3, and RG4 biological agents to supplement the BMBL, we recommend that the Policy clearly states that the local IBC has the authority to perform the risk assessment and make that determination.

19) Section IV-3: Research conducted with transgenic organisms at BSL-1/ABSL-1.
The purchase and transfer of transgenic rodents requiring BL1 containment is exempt in the NIH Guidelines (Appendix C-VII). Further, the generation of certain BL1 transgenic rodents is exempt in the NIH Guidelines (Appendix C-VIII). In 2011, NIH deemed that “… these breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective

administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk." (January 19, 2011, Federal Register, January 19, 2011 (76 FR 3150)). As documented in NIH guidance documents, the subsequent use of these BL1 transgenic rodents is also exempt (https://osp.od.nih.gov/wp-content/uploads/2022/11/Animal_Activities_Table.pdf). The same risk assessment should apply today, and the Policy should not require that work with transgenic rodents that can be housed at ABSL1 be approved by the IBC.

As noted previously, there is no definition of organism in the Policy. Therefore, we recommend changing this to animal in this section. We understand that research with some transgenic animals may not have had the time to demonstrate the same safety track record as transgenic rodents and therefore should continue to require IBC approval before that research is conducted. We would recommend that NIH seriously consider that transgenic fruit flies or zebrafish could be exempted due to their safety track record. We recommend that this be re-written as: Research conducted with transgenic animals, other than transgenic rodents, fruit flies, and zebrafish that may be housed at minimum BSL-1/ABSL-1/ACL-1.

20) Section IV-3: Research with genetically modified RG1 biological agents.
Certain research not requiring NIH-OSP approval and not involving DNA from RG3, RG4, or restricted organisms with specific risk group 1 biological agents is exempt in the NIH Guidelines (Appendices C-II, C-III, C-IV, and C-V), having been determined by the NIH Director to not present a significant risk to health or the environment. The Category here (research with genetically modified RG1 biological agents) is in contradiction to this determination and would require that work that was previously exempt now requires IBC approval. The Policy has not described why this risk assessment has changed.
We recommend that this category be removed from the Policy. Additionally, a list of RG1 biological agents is not available. If any part of the Policy references RG1 biological agents, including as work that is outside the scope of the Policy, a list should be developed and published by NIH as part of this Policy, or the local IBC should be granted the authority to designate agents as RG1.

21) Section IV-3: Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes.
This category of research is of low biosafety and biosecurity risk. The Policy fails to describe how regulating this research will increase biosafety or biosecurity. This category will set entities up for failure, with no clear benefits to our biosafety programs. Registering research with plasmids will lead to extensive unintentional noncompliance. Researchers generate plasmids regularly and the requirement to obtain approval for these plasmids from the IBC will be a severe bottleneck.
The Policy fails to describe the extent of what is required to be registered as part of this section. Only the plasmid backbone? The backbone with every gene the researcher will insert? The backbone with every gene and every mutation of that gene?
The administrative burden for researchers and the IBC will be significant and is not balanced by any increase in biological safety. We recommend that this category be removed from the Policy.

22) Section IV-3: Research with well-characterized cell lines.
Registering work with well characterized cell lines will lead to extensive unintentional noncompliance. The administrative burden will be crippling for researchers and IBCs. This category will set entities up for failure, with no clear benefits to our biosafety programs. The Policy fails to describe the biosafety

concern that is being addressed by this category of research. The Policy does not describe the extent of what is required to be registered. It is solely that a researcher is performing work with cell lines? Is it every cell line that the researcher will work with? May the entire ATCC catalogue be approved? We recommend that this category be removed from the Policy.

23) Section IV-3: Research with biological toxin proteins not on the Select Agent list.
Under the definition within the Policy, this category includes food allergens, animal allergens, even FBS, since they can cause harm to humans, yet there is no indication that this is intended. The milk that a researcher is using as part of a Western blot falls within scope of this category.
There is a conflict between the wording in this Section (research with biological toxin proteins) and the definition in the Policy for Toxin (a protein or peptide produced …). This conflict makes it difficult to understand what is within the scope of the category.
This category of research must include a clear definition of which toxins are within scope, including an LD50, or entities will be inadvertently noncompliant.
At our institution, work with toxins are already regulated by our Chemical Safety Committee, which provides regulatory oversight of this work. Additional oversight by the IBC will not increase safety and will instead increase regulatory burden.
We recommend that this category be removed from the Policy. If this category is not removed, we recommend that this be re-written as: Research with biological toxin proteins with an LD50 in vertebrates of <100 micrograms per kilograms of body weight.
Additionally, a list of toxins currently classified under this category must be provided in the Policy. The list of toxin molecules classified as to LD50 that is currently available from NIH OSP under the NIH Guidelines (Appendix F-1) should serve as the backbone of this list.

3. Continued utility of Risk Groups: 1) Risk Groups as Hazard Characterizations vs. Site-Specific Risk Assessment .
Risk Groups remain valuable tools for initial hazard communication and agent characterization, but they should not independently dictate containment or review levels. The final policy must preserve site-specific and experiment-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations. This aligns with Section V-E of the draft policy, which explicitly acknowledges that Risk Groups and Biosafety Levels are related but non-equivalent concepts.
2) Critique of Mandatory IBC Petitions for Emerging, Novel, or Unlisted Agents (Section III-B) .
The 'IBC Functions' section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents 'for which the RG classification or containment level is not available in the BMBL,' prohibiting IBC approval until authorized by NIH and any other applicable entities.
3) Terminology Inconsistency: The draft text treats 'RG classification' and 'containment level' as alternative terms residing in the BMBL. However, Section V-E correctly states that RGs and BSLs are non-equivalent. NIH must use these terms consistently across all policy sections.
4) BMBL Functionality & Misconception: The Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual does not assign Risk Groups; it provides Agent Summary Statements with recommended Biosafety Levels. A regulatory condition referring to an RG classification 'in the BMBL' cannot be fulfilled.
5) Jurisdictional Ambiguity: The phrase 'and any other applicable Federal, State, or local entities' introduces immense ambiguity. NIH must explicitly identify these entities, specify whether approvals are

sequential or concurrent, clarify coordination protocols, and establish resolution pathways when determinations conflict.
6) Overbroad Scope & Unintended Petition Backlogs: As written, the petition requirement could be interpreted as applying to non-pathogenic genetically modified constructs or benign RG1 organisms that are not explicitly named in the BMBL. NIH must explicitly clarify that unlisted, non-pathogenic RG1 agents do not require federal petitioning.
7) Reusable Determinations & Response SLAs: Section III-D commits NIH to publishing determinations for lowering RG3/RG4 containment but omits determinations for emerging or novel agents. NIH should publish all containment determinations (agent, modification, approved containment, and rationale) in a searchable public database that other institutions may rely upon as established precedent. Furthermore, NIH must set a target response timeline (e.g., 30 calendar days) rather than relying on the subjective term 'timely.'
8) Definitive Source for Risk Group Assignments.
With Risk Group assignments removed from the former Appendix B and absent from the BMBL, NIH must provide an authoritative, version-controlled federal repository or clear objective criteria for assigning Risk Groups to non-recombinant agents. Without standardized federal classifications, institutions will reach conflicting conclusions for the same agent, compromising national oversight consistency.
9) Avoid Rigid Containment Prescriptions (GDMOs and Influenza Research). Rigid, one-size-fits-all containment rules conflict with performance-based risk assessment. A universal minimum of BSL-2 for Gene Drive Modified Organisms (GDMOs) does not map effectively to specialized containment systems (e.g., Arthropod Containment Level [ACL] guidelines, USDA/NCAR Greenhouse standards, or aquatic facilities). NIH should permit equivalent risk-based containment modalities and issue specialized guidance. Additionally, containment mandates for influenza constructs should specify exact phenotypic traits, host range, and pathogenicity markers rather than sweeping in constructs based on raw genomic segment proportions.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): None

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1) Refine the definition of a reportable incident and provide clearer thresholds for reporting to support a risk-based, consistent approach across institutions. Clear thresholds improve consistency and allow NIH to focus regulatory oversight on events with true potential public health or community significance.
2) Decouple Regulatory Reporting from Public Website Posting: Requiring institutions to publicly post unredacted investigative reports and meeting minutes for routine or minor incidents creates severe unintended consequences:
3) Publicly posted incident reports inadvertently provide sufficient detail to identify involved personnel.
4) Publicly linking Principal Investigators, grant numbers, and specific facility locations exposes researchers to harassment, physical threats, and targeted cyber-attacks, particularly in sensitive animal research domains.
5) Aggregated public postings reveal institutional research security information. Automated AI scraping tools can harvest these public records to map national high-consequence research capabilities, directly conflicting with federal research security directives and Select Agent regulations.
6) Forcing minor, fully mitigated events into public view suppress internal reporting of near-misses and

borderline events out of fear of public backlash or reputational damage.
7) Resolving Undefined Categories & Technical Definitions: To eliminate ambiguity, prevent administrative overload, and protect local reporting culture, NIH must establish precise definitions for the following core terms in Section II:
Incident: A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.
Release (Loss of Containment or Occupational exposure): Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
Basic First Aid vs. Agent-Specific Medical Treatment: NIH must explicitly align medical treatment with OSHA standards (care beyond basic first aid). NIH must clarify that precautionary, non-specific post-exposure prophylactic (PEP) treatment or routine medical consultations do not constitute agent-specific treatment triggering 24-hour federal reporting.
Potential Exposure: Must be defined as an event occurring in the active presence of a biohazard where primary barriers or PPE were breached, creating a credible exposure pathway. Equipment or PPE failures occurring in the absence of active biohazardous agents are not potential exposures.

8) Compliance Violation vs. Administrative Non-compliance: Must distinguish administrative non-compliance (e.g., late paperwork, minor log errors) from substantive biosafety non-compliance (e.g., unapproved research initiation or unauthorized containment lowering). Administrative non-compliance and low-risk items must NEVER necessitate a 24-hour reporting timeframe.

9) Minor Spill: Must remove subjective terms like generally and define minor spills.
10) Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries.
11) NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports

6. Other feedback relevant to this resource: 1) Provide risk assessment guidance for self-aggregating proteins (Policy Sections II and V-A). The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.
2) Clarify oversight of computational and AI assisted work (Policy Sections II and V-C). Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological
3) Provide a minimum 24-month phased implementation period The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction

standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.
4) Pilot the policy and templates: NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.
5) Develop implementation resources: Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.
6) Address the cost of compliance: The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.
7) Allow flexible institutional models: The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

I thank NIH for allowing me the opportunity to provide comments on this Draft Policy. We look forward to seeing a second draft of the Policy and will remain fully engaged in this process.

Description: Comments to NIH biosafety policy

232. William Redmond

I am responding: On behalf of myself

Name: William Redmond

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer Immunotherapy

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Draft-NIH-Biosafety-Policy-for-Research-Involving-Biohazards_comment_WR.docx

Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Submitted to: National Institutes of Health, Office of Science Policy
Re: NOT-OD-26-112 — Draft NIH Biosafety Policy for Research Involving Biohazards
Date: October 15, 2026
Submitted by: William L. Redmond, PhD
Portland, Oregon

General Comments

I appreciate the opportunity to comment on the proposed NIH Biosafety Policy for Research Involving Biohazards. I strongly support NIH's objective of modernizing biosafety oversight and ensuring that research involving biological materials is conducted safely and responsibly. The proposed shift toward risk-based oversight, including provisions for delegated Institutional Biosafety Committee (IBC) review, is an important and welcome development.

I strongly believe that effective regulation must be grounded in scientific evidence, practical experience, and the actual biological risks associated with specific research activities. Rigorous biosafety oversight is essential, particularly when introducing novel technologies with uncertain risks. However, requirements appropriate for pioneering, higher-risk research should not automatically be extended to routine laboratory procedures that have been performed safely for decades under established institutional practices.

My principal concern is that the proposed expansion of IBC oversight could substantially increase administrative requirements for routine research involving primary human specimens, established cell lines, and well-characterized genetic modifications without providing corresponding improvements in safety. Such requirements could divert limited institutional resources from oversight of genuinely higher-risk activities, delay scientific discoveries, increase research costs, and ultimately impede the translation of promising treatments to patients with cancer.

The proposed expansion of IBC oversight must also be considered in conjunction with the policy's requirements for documentation and public disclosure of IBC proceedings. Bringing substantially more routine biomedical research under IBC review could significantly increase administrative burdens and create additional risks of inadvertent disclosure of unpublished scientific discoveries, proprietary research methods, intellectual property, and confidential research information.

I therefore encourage NIH to adopt a framework that preserves rigorous oversight of research presenting meaningful biological hazards while providing streamlined, risk-based review pathways for routine biomedical research. The following recommendations are intended to strengthen the proposed policy while maintaining the efficiency and innovation essential to translational biomedical research.

1. Research Involving Primary Human Specimens

Relevant provision: Section IV-2 — Research Requiring IBC Review and Approval Before Initiation

The draft policy identifies research involving primary cells that may be contaminated by adventitious agents as requiring IBC review and approval before initiation.

This provision could encompass an extraordinarily broad range of biomedical research, including routine laboratory studies involving peripheral blood mononuclear cells (PBMCs), lymphocytes, human tumor biopsies, surgical specimens, tumor-infiltrating lymphocytes (TILs), primary tumor cultures, and patient-derived organoids.

These materials are essential to contemporary translational cancer research and are routinely handled under established institutional biosafety practices, including appropriate BSL-2 precautions and universal precautions for potentially infectious human specimens.

Although primary human specimens can contain adventitious infectious agents, the mere possibility of such contamination should not automatically require separate protocol-specific review by the full IBC.

It is important to distinguish between routine handling of potentially infectious human specimens and experimental procedures that intentionally propagate infectious agents, increase exposure risks, or introduce additional biological hazards.

Recommendations

A. Establish streamlined institutional review mechanisms.

NIH should permit institutions to approve routine collection, processing, culture, and analysis of primary human specimens through institution-wide or laboratory-specific biosafety registrations.

Such approvals could cover defined classes of specimens and experimental procedures rather than requiring separate IBC submissions for every scientific research protocol.

B. Permit delegated review of routine human specimen research.

Routine research involving primary human tissues and cells should be eligible for delegated review by an institutional biosafety officer or designated IBC member when established containment procedures are appropriate and no additional biological hazards have been identified.

C. Reserve full IBC review for activities involving increased biological risk.

Full IBC review should be required when experimental procedures introduce hazards beyond those associated with routine specimen handling, including intentional propagation of infectious

agents, modifications increasing pathogenicity or transmissibility, or procedures requiring higher levels of containment.

D. Clarify the meaning of "may be contaminated by adventitious agents."

Without additional clarification, this language could encompass virtually all primary human specimens. NIH should specify how institutions should evaluate the likelihood and consequences of contamination and whether routine BSL-2 practices adequately mitigate the associated risks.

Suggested Policy Language

"Research involving routine collection, processing, culture, or analysis of primary human cells and tissues, including blood-derived cells and tumor specimens, may be reviewed and approved through an institutional biosafety registration or delegated review process when the activities are conducted under established containment practices and do not involve intentional propagation of infectious agents or other procedures introducing additional biological hazards.

Separate protocol-specific IBC approval shall not be required for activities covered by an approved institutional or laboratory-specific biosafety registration, provided that the activities remain within the scope of the approved risk assessment."

2. Research Involving Established Human Cell Lines

Relevant provision: Section IV-3 — Research Eligible for Delegated Review

The proposed policy appropriately recognizes that research involving well-characterized cell lines may be eligible for delegated review.

This is an important distinction because established human cell lines are among the most widely used experimental systems in biomedical research.

Cancer research laboratories routinely employ established tumor cell lines for studies of antigen expression, immune recognition, tumor biology, drug sensitivity, vaccine development, and mechanisms of resistance to immunotherapy.

These studies may involve hundreds of experimental variations using the same cell lines without materially changing the underlying biosafety risks.

Requiring repeated biosafety submissions for routine experimental modifications would add administrative burden without necessarily improving laboratory safety.

Recommendations

A. Establish a clear definition of well-characterized cell lines.

NIH should clarify that well-characterized cell lines include established human and animal cell lines with documented identity, provenance, and appropriate biosafety characterization.

The definition should not depend solely on whether a cell line was obtained from a commercial repository. Research laboratories frequently develop and maintain extensively characterized cell lines that are not commercially distributed.

B. Permit laboratory-wide registration of established cell lines.

Institutions should be permitted to approve the use of defined categories or collections of established cell lines under a single laboratory biosafety registration.

Addition of another cell line with an equivalent risk profile should not automatically require a new IBC protocol.

C. Exempt routine experimental changes from repeated review.

Changes in culture media, cytokine exposure, drug treatment, antigen expression analysis, immune-cell coculture, and similar procedures should not require additional IBC approval unless they materially alter the biological hazard.

D. Differentiate established cell lines from cell lines with specific hazards.

Full IBC review should remain available for cell lines containing replication-competent pathogens, producing infectious agents, or presenting other identifiable risks requiring enhanced containment.

Suggested Policy Language

"Research involving well-characterized established cell lines may be conducted under laboratory-specific or institutional biosafety registrations approved through delegated review.

Routine experimental modifications, including changes in culture conditions, noninfectious treatments, and cellular assays, shall not require additional IBC review unless they introduce new biological hazards or materially alter the approved biosafety risk assessment.

Institutions may establish procedures for adding cell lines with equivalent biosafety characteristics to an existing approved registration."

3. Research Involving Genetically Modified Cells and Viral Vectors

Relevant provisions: Sections IV-2, IV-3, and V-B

The proposed policy requires IBC review for research involving genetically modified cells, viruses, and organisms while allowing delegated review for certain lower-risk experiments, including those involving genetically modified Risk Group 1 agents and replication-incompetent, nonintegrating viral vectors expressing low-risk transgenes.

I support the concept of tiered oversight. However, the proposed distinctions may not adequately reflect the diversity of genetic engineering methods routinely used in contemporary biomedical research.

Genetic modification is now a standard laboratory technique employed to investigate gene function, tumor antigen expression, immune recognition, cellular differentiation, and mechanisms of disease.

Examples include expression of tumor-associated antigens or noncanonical proteins in established cell lines, introduction of T-cell receptors into cultured lymphocytes, CRISPR-mediated gene knockout or modification, transient expression of reporter genes, use of replication-defective lentiviral or retroviral vectors, and genetic modification of tumor cells for studies of immune recognition.

These approaches have markedly different biological risk profiles.

The use of genetic modification alone should not determine whether a protocol requires full IBC review. Instead, the level of oversight should reflect the actual hazards associated with the modified cells, vectors, expressed products, and experimental procedures.

Recommendations

A. Expand delegated review to additional categories of low-risk genetic modification.

NIH should consider extending delegated review eligibility to well-characterized replication-defective integrating vectors, including selected lentiviral and retroviral vector systems, when the overall risk assessment supports this approach.

Although integration introduces additional considerations, it does not necessarily justify full IBC review for every experiment.

B. Differentiate genetic modifications according to their biological consequences.

The risk assessment should consider whether a modification increases pathogenicity or transmissibility, produces an infectious or replication-competent agent, alters host range or tissue tropism, introduces a toxin or other hazardous gene product, or otherwise increases risks to laboratory personnel or the environment.

Routine expression of nonhazardous proteins, reporters, or tumor antigens should generally qualify for streamlined review.

C. Permit platform-based approvals for commonly used vector systems.

Institutions should be able to approve defined vector platforms and associated laboratory procedures through a single biosafety registration.

For example, a laboratory routinely using a characterized replication-defective lentiviral vector platform to express nonhazardous proteins should not require an entirely new IBC protocol for each transgene, provided the new construct does not materially change the biosafety risk assessment.

D. Establish a streamlined amendment process.

Minor changes involving nonhazardous transgenes, reporter constructs, or experimental targets should be eligible for administrative or delegated review.

Full IBC review should be reserved for modifications that materially increase biological risk.

E. Distinguish genetically modified producer cells from final investigational products.

In cancer vaccine and cell therapy development, genetically modified cells may be used to manufacture products that do not themselves contain viable genetically modified cells or replication-competent vectors.

NIH should clarify that biosafety assessments of manufacturing activities and final products should be based on their respective hazards.

A final nonreplicating, nonintegrating, cell-derived vaccine product should not automatically be assigned the same biosafety risk classification as the genetically modified cells used during its manufacture.

Suggested Policy Language

"Research involving genetically modified cells or viral vectors shall be assigned to an appropriate level of oversight based on the biological characteristics of the modified material, the properties of the introduced genetic elements, the potential for replication or dissemination, and the risks associated with the proposed experimental procedures.

Delegated IBC review may be used for research involving well-characterized replication-defective vector systems and genetic modifications that do not materially increase biological hazards, when supported by a documented institutional risk assessment.

Institutions may approve established genetic modification platforms through laboratory-specific biosafety registrations. Changes in transgenes or experimental constructs that do not materially alter the approved risk assessment may be addressed through streamlined amendment procedures."

4. IBC Documentation, Public Disclosure, and Protection of Confidential Research Information

Relevant provisions: Delegated IBC Review, IBC Meeting Minutes, and Public Disclosure Requirements

The proposed NIH Biosafety Policy would require actions approved through delegated review to be reported "in full" at the next scheduled Institutional Biosafety Committee meeting and documented in the meeting minutes. The policy also provides for public posting of approved IBC meeting minutes, subject to allowable redactions.

While transparency and institutional accountability are important objectives, these provisions raise significant concerns regarding the disclosure of unpublished scientific research, intellectual property, proprietary research methods, confidential personnel information, and laboratory security-sensitive information.

These concerns are particularly important for translational biomedical research institutions conducting innovative research in cancer immunotherapy, vaccine development, genetic engineering, and investigational therapeutics, frequently in collaboration with biotechnology companies and pharmaceutical partners.

IBC protocols may contain detailed descriptions of experimental approaches, unpublished discoveries, novel constructs, proprietary manufacturing methods, and research strategies that have not yet been patented or publicly disclosed.

Public disclosure of such information could compromise intellectual-property protection, interfere with scientific publication, undermine contractual confidentiality obligations, and discourage academic-industry collaborations.

In addition, IBC records may contain information concerning laboratory locations, biological agent inventories, occupational-health considerations, personnel responsibilities, and security measures that should not be disclosed publicly.

The requirement that delegated approvals be reported "in full" is particularly concerning because it is unclear whether this refers to a complete description of the underlying research protocol or a complete accounting of the IBC's review and approval actions.

NIH should explicitly distinguish between complete internal documentation of biosafety decisions and the information necessary for meaningful public transparency.

Recommendations

A. Define the minimum information required in publicly posted IBC minutes.

NIH should establish clear and consistent standards identifying the information necessary to document IBC oversight and institutional accountability.

Public records should document the committee's actions, including quorum, recusals, risk determinations, approval conditions, and voting outcomes, as applicable, without requiring disclosure of confidential protocol-level scientific information.

B. Clarify the meaning of reporting delegated approvals "in full."

NIH should specify that this requirement refers to a complete accounting of delegated review decisions, including the nature of the activity, applicable risk classification, approval determination, and any conditions of approval.

It should not require public disclosure of complete research protocols, experimental methods, genetic constructs, unpublished findings, or other confidential scientific information.

C. Establish explicit and consistent redaction standards.

The final policy should authorize appropriate redaction of information involving unpublished scientific discoveries, patentable inventions, intellectual property, trade secrets, proprietary experimental methods, confidential sponsor information, personally identifiable information, occupational-health information, biological agent inventories, sensitive laboratory locations, facility vulnerabilities, and security controls.

NIH should provide clear guidance to promote consistent implementation across institutions and minimize uncertainty regarding permissible redactions.

D. Establish a reasonable period for public posting.

The requirement for immediate posting of approved IBC minutes could create substantial administrative and compliance burdens.

Institutions require sufficient time to conduct appropriate privacy, intellectual-property, security, legal, and communications review before releasing documents publicly.

NIH should establish a reasonable, defined posting period following approval of meeting minutes rather than requiring immediate publication.

E. Permit standardized public summaries while retaining complete internal records.

NIH should permit institutions to prepare standardized public summaries of IBC proceedings that provide meaningful information about biosafety oversight without disclosing confidential or security-sensitive information.

Complete, unredacted meeting minutes, protocol submissions, risk assessments, and supporting documentation should be maintained internally and made available to NIH and other authorized oversight authorities as required.

This approach would preserve regulatory accountability while reducing the risks associated with public disclosure.

Suggested Policy Language

"Institutions shall maintain complete internal records of IBC proceedings, delegated reviews, risk assessments, approval determinations, and associated supporting documentation.

Publicly available IBC records may consist of appropriately redacted meeting minutes or standardized summaries that document committee actions, risk classifications, approval decisions, conditions of approval, quorum, recusals, and voting outcomes, as applicable.

Reporting delegated approvals 'in full' shall require a complete accounting of the review actions and determinations but shall not require public disclosure of complete research protocols or confidential scientific, proprietary, personnel, occupational-health, or security-sensitive information.

NIH shall establish uniform standards for permissible redactions and a reasonable period following approval of IBC minutes for institutions to complete appropriate confidentiality, intellectual-property, privacy, legal, and security reviews before public posting.

Complete, unredacted records shall be retained by the institution and made available to authorized oversight authorities as required."

5. Avoiding Duplicative Oversight and Unnecessary Administrative Delays

An overarching concern is the potential for duplicative oversight across institutional review systems.

Biomedical research institutions already maintain established processes involving Biosafety Committees, occupational-health programs, Institutional Review Boards, Institutional Animal Care and Use Committees, and other research compliance offices.

For studies involving investigational therapies, additional oversight is provided through FDA requirements and institutional clinical research governance.

Although these systems serve different purposes, unnecessary duplication of administrative review should be avoided.

NIH should explicitly encourage coordinated review and recognition of existing institutional risk assessments.

In addition, NIH should establish clear expectations for timely delegated review and distinguish between modifications that require prospective approval and routine changes that can be documented within an existing approved protocol.

NIH should provide model umbrella registrations, model public summaries, redaction examples, and implementation guidance before the policy becomes effective.

6. Conclusion and Requested NIH Actions

The proposed NIH Biosafety Policy presents an opportunity to modernize biosafety oversight while improving the efficiency of biomedical research.

I support NIH's objective of strengthening biosafety through a scientifically grounded, risk-based framework. However, achieving that objective requires distinguishing research involving meaningful biological hazards from routine laboratory procedures conducted under well-established containment practices.

I encourage NIH to incorporate the following principles into the final policy:

1. Permit institution-wide or laboratory-specific biosafety registrations for routine studies involving primary human specimens.
2. Expand delegated review eligibility for low-risk research involving human tissues, established cell lines, and well-characterized genetic modifications.
3. Allow platform-based approvals for established cell culture and viral vector systems.
4. Require additional IBC review only when experimental changes materially alter the underlying biosafety risk assessment.
5. Distinguish the risks associated with genetically modified manufacturing systems from those associated with final investigational products.
6. Establish clear standards for public disclosure of IBC proceedings, including minimum reporting requirements, permissible redactions, and reasonable timelines for public posting.
7. Permit standardized public summaries of IBC decisions while requiring institutions to retain complete, unredacted records internally, thereby protecting unpublished scientific discoveries, intellectual property, confidential personnel information, and laboratory security-sensitive information.
8. Promote coordination with existing institutional and federal oversight systems to avoid unnecessary duplication and delays.

NIH has an opportunity to establish a modern framework that directs regulatory attention and institutional resources toward research presenting meaningful biological risks while allowing routine biomedical research to proceed efficiently under established safety practices.

The success of this policy should ultimately be measured not by the number of protocols subjected to review, but by its effectiveness in protecting research personnel, patients, and the public while enabling responsible scientific innovation.

Regards,

William L. Redmond, PhD

NIH Policy References

NIH Notice NOT-OD-26-112:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

NIH Office of Science Policy — Biosafety and Biosecurity Policy:
https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/

NIH Public Comment Portal:
https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

233. Gregory Park

I am responding: On behalf of myself

Name: Gregory Park

Name of Organization: University of Minnesota

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Life science research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Appropriate attempt, but clarifications are needed in the definitions, or if there is flexibility within the scope, then statements must be made that allow institutional flexibility in the interpretation and application of scope with the spirit of the Policy in mind. Describing scope is a difficult process because there are exceptions that present both high and low risk situations that are just not easy to account for in policy language.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered oversight is important, and empowering local oversight is most important for this NIH Biosafety policy. I think your draft does an acceptable job of this. Unfortunately, I think many comments are going to be submitted that bring up perceived gaps in the NIH Biosafety Policy because no institution or organization subject to the policy wants to get it wrong. Without some language that pardons institutions/organizations from making decisions to fit their circumstances in the spirit of the policy that was written (protection of human health, transparency, etc.), groups are going to be filling your comment sections with requests for clarifications and specific needs so they can ensure that they are not making wrong decisions and are then subject to penalties. And, the policy does not seem to explicitly state that local oversight should make decisions for all perceived gaps in order to implement the policy framework. The recommendations to gain clarity and make decisions result in making interpretation so complicated, it actually raises more questions and takes power away from local oversight. It also makes implementation more difficult for institutions and groups that vary in size and scope of research, but yet are subject to the Policy.

3. Continued utility of Risk Groups: Risk group utility is an important baseline that should be used, but there is not a standard federal reference document that labels every agent with a risk group nor modified agents, naturally occurring variants, and emerging/novel agents. Additionally, use of BSL from the BMBL also doesn't always account for modified agents, all naturally occurring variants/strains, and appropriate BSL flexibility guidance. Thus, the IBC is a great way to allow local decision making. If the NIH Guidelines and BMBL are continually used as a references for guidance in many situations, but not as strict decision makers, then IBCs should be afforded the flexibility to make decisions as they see fit. If

anything, a set of guidelines that describe when certain BSL must be followed, may be a better way to keep high risk research from unusual IBC decisions that fall outside the spirit of the NIH Biosafety Policy.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: With changes in software, accessibility, compatibility, and institutional size, the strict adherence to incident reporting and meeting minutes templates is not ideal. It is better to offer up that components of these should be included, but use of the templates should be optional.

6. Other feedback relevant to this resource: I think many comments will be submitted that want empowerment of BSOs. BSOs, as a role on the IBC with specific duties mutated from their introduction to became the focus and pinnacle position for an entire industry, where the spirit of the role was changed to something authoritarian as biosafety professionals seemed to feel they would only be listened to in requesting resources and assistance if they had a powerful title. I think the empowerment of the BSO is misguided, but the plight is real. Some want to believe the BSO is akin to an Attending Veterinarian or a Chief of Police and want a federal agency to say as much. What is more important is ensuring that biosafety expertise of a certain kind is necessary and involved when research of a certain kind is being performed. Too often, biosafety professionals do not recognize the biosafety expertise of the faculty at institutions who simply need to be informed of a different lens when considering safety, and even worse, they find them as adversaries instead of partners. Instead of spending time empowering BSOs in the NIH Biosafety Policy, biosafety professionals need to seek out stronger collaborations with their IBCs to empower biosafety compliance and seek out resources with institutional administration.

234. Kai Zhang

I am responding: On behalf of myself

Name: Kai Zhang

Name of Organization: Texas Tech University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): molecular microbiology, infectious diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Biohazard definition is TOO broad. The vast majority of the biomaterial in research pose minimal hazard.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Not at all appropriate. Too much overnight. Waste of time and resources at every level.

3. Continued utility of Risk Groups: it is fine

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): not needed

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Not necessary to have a uniform template

6. Other feedback relevant to this resource: It is mostly useless and unnecessary

235. University of Idaho

I am responding: On behalf of an organization

Name: Russell McClanahan

Name of Organization: University of Idaho

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Academic research with biohazardous materials

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Description: NIH Biosafety Draft Policy Comment Letter from University of Idaho Vice-President of Research and Economic Development

236. University of Idaho

I am responding: On behalf of an organization

Name: Russell McClanahan

Name of Organization: University of Idaho

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Academic Research with Biohazardous Materials

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: • The Scope (p. 3) explicitly excludes plants from items 2 and 4 ("cells, viruses, or organisms, other than plants…"). If the intent is to cover genetically modified plants, the language should be revised to remove "other than plants" or include a separate plant-specific provision.
• If genetically modified plants are intentionally excluded, the policy should clarify which oversight mechanism or regulatory body is responsible for monitoring these activities to avoid potential gaps in oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed framework expands committee reviews, mandates three-year protocol renewals, requires public posting of minutes and incident reports, and extends requirements to all NIH-funded institutions. We urge NIH to ensure these administrative burdens are proportionate to the safety benefits through a risk-based approach.

Specifically, we recommend the following:
• Compliance Violations: The requirement to report "any compliance violations" is overly broad. NIH should provide specific examples (e.g., failure to obtain IBC approval, containment breaches) and clarify reporting pathways.
• BSO Role: We suggest additional guidance on the BSO's authority to suspend risky activities, their responsibility for equipment records, and coordination with occupational health. We also suggest requiring a BSO for BSL-2 labs working with DGOF agents.
• Training & Near Misses: Clarify if PIs may conduct training independently or if BSO/IBC involvement is required and define minimum standards. Regarding near-miss reporting to NBDSAC, please clarify the designated submitter and whether local records should feed into a national repository.
• Public Disclosure: Publicly posting all incident reports may discourage candid self-reporting due to reputational risks. We suggest balancing transparency with the need to maintain a strong reporting culture

3. Continued utility of Risk Groups: The policy requires that risk assessments be available (pp. 5-6) and IBC approvals be documented in meeting minutes (pp. 6-7). We request guidance on whether full risk assessments should be included in posted minutes, referenced via a link/identifier, or stored in a separate public repository. Clear expectations will promote consistency and reduce administrative burden.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The University of Idaho supports efforts to encourage voluntary adoption of biosafety best practices for research not otherwise subject to the policy. Clear guidance, streamlined reporting mechanisms, and educational resources may promote broader participation without creating unnecessary administrative burden.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We support the draft incident reporting template for its concise approach to consistent data collection. Regarding the other templates/requirements, we suggest the following:

• Minutes Template: The current level of detail is burdensome and often duplicates information found in approved protocols. We encourage a more streamlined format that focuses on committee deliberations and decisions rather than recreating redacted protocols.
• Posting Timeline: Please clarify if draft minutes must be posted publicly before approval, or if only approved minutes should be posted following the subsequent meeting (pp. 6-7).
• Basic First Aid: For incidents requiring only first aid (Section III.B), we suggest NIH define "basic first aid" or reference an authoritative resource and clarify any associated documentation requirements.

6. Other feedback relevant to this resource: The University of Idaho believes additional implementation guidance would be most valuable in the areas discussed above, including:
• Public posting of meeting minutes and expectations regarding draft versus approved minutes.
• Definitions and documentation requirements associated with basic first aid.
• Reportable compliance violations and reporting pathways.
• Biosafety Officer authority and responsibilities.
• PI training responsibilities and minimum training expectations.
• Near-miss reporting responsibilities and local recordkeeping expectations.
• Availability and public accessibility of risk assessments.

Description: NIH Biosafety Draft Policy Comment Letter from University of Idaho Vice-President of Research and Economic Development

237. Helen Rappe Baggett

I am responding: On behalf of myself

Name: Helen Rappe Baggett

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Some scope of work requiring IBC review is not well defined, and these definitions should be tied to biosafety hazard.

-Research with prions or other self-aggregating proteins
-Research with well-characterized cell lines
-Primary cells that may be contaminated by adventitious agents.
It is unclear if this would include ALL work with primary human cells or NHP cells or tissues.

Additionally, this policy does not permit any exemptions. Work that was previously exempt from review under the NIH Guidelines Section F will now require IBC review, including all plasmids and transgenic animals. This will add significant administrative burden without meaningfully impacting safety. It is recommended that NIH maintain the previously established categories of exempt research. NIH describes the purpose of the modernization as expanding oversight to biohazards while "removing red tape for low-risk research" and specifically asks commenters whether the proposed tiered oversight is appropriately calibrated to risk and administrative burden.
Exempt from IBC oversight is not synonymous with exempt from safe laboratory practice. Rather, it represents a determination that the incremental safety benefit of mandatory IBC oversight does not justify the administrative burden for a defined class of low-risk research. Currently exempt research was previously determined by NIH, following notice and opportunity for public comment, not to present a significant risk to health or the environment.

Update this draft policy to include exemptions for materials with a commonly understood low biosafety risk, such as well-characterized cell lines, presumed non-infectious primary cells/tissues, previously exempt transgenic animals, and vectors with no toxic or otherwise harmful inserts.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Risk Group must continue to be used as a baseline for risk assessment. Risk assessments for modifications to agents must have a starting point, and the risk group

for the wildtype agent is the logical starting point. Wildtype Risk Group should not be the default assumption for modified agents, but it provides a baseline of risk assessment that the expertise present in the IBC can use when deliberating whether the modifications enhance or decrease the risk of the agent. Only when the Risk Group is set can the appropriate Biosafety Level be assigned.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident Reporting: Requiring public posting of incidents is a bad idea. Adding in the requirement to identify the PI is even worse. This will only result in fewer incidents being reported, which means that biosafety professionals will not be able to identify trends and implement mitigation strategies, which means that more incidents may occur as a result. I don't see this policy as anything other than a punitive measure to publicly shame labs/PIs/institutions who have incidents. It will not improve safety or prevent the accidental release of agents.

It is recommended that NIH revise the approach to public posting of incidents so that detailed incident reports are submitted to NIH but are not routinely required to be posted publicly in their entirety. Alternatively, NIH could provide a template for public posting of standardized, de-identified high level summary information of incidents that might include root-cause categories and corrective actions. NIH could separately require disclosure of additional information when a particular incident presents a compelling public health or safety interest.

This approach balances transparency objectives with the equally important need to preserve a just, non-punitive reporting culture in which researchers and staff are encouraged to report incidents, near misses, and potential safety concerns promptly and completely. It also provides protections for researchers that are increasingly threatened or harassed due to the tools or subject matter of their research. Importantly, NIH would receive the information necessary to evaluate significant incidents, institutional responses, and compliance. The distinction would therefore be between information necessary for regulatory oversight and information necessary for public transparency, rather than assuming that the same level of detail is needed for both purposes.

6. Other feedback relevant to this resource: Scope of work lacking clear definitions:

Primary cells that may be contaminated by adventitious agents.
As written, “may be contaminated” could be interpreted to include virtually any primary human or animal cells (including any research involving NHP cells or tissues) for which the infectious-agent status of the source has not been comprehensively established.
NIH should define “adventitious agent,” establish a risk-based threshold for determining when contamination is reasonably anticipated, and clarify whether donor screening, testing, source information, or other documentation can establish that primary cells do not fall within this category. The Policy should also clarify its application to commercially obtained cells, repository specimens, patient-derived cells, and primary animal cells and provide examples of included and excluded materials. A merely theoretical possibility of contamination should not independently trigger IBC oversight; the definition should be tied to a known or reasonably anticipated potential hazard to human health. Clear criteria are necessary to avoid additional administrative burden by unnecessarily expanding IBC oversight

beyond research presenting a meaningful biosafety risk.

Well-characterized cell lines.
The Policy does not provide sufficiently objective criteria for determining when a cell line qualifies as well-characterized, creating the potential for inconsistent interpretations among investigators, biosafety professionals, and IBCs. NIH should specify what level of information regarding identity, provenance, biological characteristics, and adventitious-agent testing is necessary; whether established commercially available or widely used cell lines may be presumed to satisfy the definition; and how primary, immortalized, genetically modified, and patient-derived cells should be treated. NIH should also provide examples of included and excluded cell lines. Because this determination may affect the scope and level of institutional oversight, a clear, risk-based definition is necessary to ensure consistent implementation and avoid additional administrative burden by unnecessary review of research that does not present a meaningful biosafety risk.

Self-aggregating proteins.
IBC review is appropriate for the review of research involving prions or biospecimens identified to be from a person or animal known to have a prion-based disease. However, the term self-aggregating is not sufficiently defined to permit institutions or investigators to determine consistently if every protein that happens to aggregate or contributes to an aggregation-associated human disease, such as ALS, is also covered. Protein aggregation alone does not necessarily establish a meaningful biosafety hazard. NIH should clarify whether “other self-aggregating proteins” is intended to encompass proteins with prion-like, seeding, propagation, transmissibility, pathogenic, or other specified hazard characteristics rather than any protein capable of aggregation. The definition should identify objective criteria and provide examples of both covered and excluded materials.

Timeline for Implementation.
The timeline for institutional implementation and compliance with the revised policy should be at least a year after the publishing of the final rule instead of 6 months.
A six-month implementation period is insufficient given the breadth, complexity, and institutional impact. Revising electronic systems to accommodate the new regulations is a significant challenge that will likely prevent many institutions’ ability to meet this timeline. Additionally, updating policies and procedures and ensuring that researchers have the training they need to understand the new requirements, including newly covered areas of research, will require additional time. The time required to identify newly covered research is one reason why it is critical for entities to be held to realistic and achievable implementation timelines.

NIH should provide a detailed description of the required elements of an institutional assurance and publish accompanying implementation guidance before policy adoption, including model assurance language, implementation templates, and sufficient lead time for institutions to develop. Administrative burden should be kept in mind in considering required elements.

Human subjects' studies requiring IBC review.
Section IV-2 outlines the only clinical research provision and specifically identifies IBC review for biohazards that shed, replicate, integrate, require higher-risk manipulation, or involve RG2 or higher

wild-type agents. There is no discussion of other genetically modified agents being used in clinical research, such as plasmids or RNA, and no discussion of exemptions. Given the https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative.html, additional administrative burden should not be introduced by expanding IBC oversight in the clinical research arena.

The Policy should also exempt any covered clinical research studies from mandatory three-year de novo IBC review or permit an administrative continuation process confirming that no material changes affecting biosafety have occurred. Full IBC review should be required only for clinical research presenting local biosafety risk, where there may be questions regarding product handling and possible shedding. This approach would maintain appropriate biosafety oversight while reducing unnecessary regulatory burden

238. Sonia Rosenberger DVM, MSOH, CBSP

I am responding: On behalf of myself

Name: Sonia Rosenberger DVM, MSOH, CBSP

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/15/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious disease - basic research, treatment and prevention

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attachment.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I did not comment on this topic.

3. Continued utility of Risk Groups: I did not comment on this topic.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I did not comment on this topic.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attachment.

6. Other feedback relevant to this resource: Please see attachment.

Uploaded File: 2026-10-NIH-biosafety-policy-comments-SRosenberger.docx

National Institutes of Health (NIH) Draft Biosafety Policy for Research Involving Biohazards, dated 8/19/2026 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

The new biosafety policy incorporates major components of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) while adding pathogens and materials that could negatively impact human health that many Institutional Biosafety Committees (IBCs) already review. Therefore, these comments solely include suggestions for clarification or revision. Thank you for the opportunity to review and your consideration.

For context, continued overlap:

- Human Immunodeficiency Virus, Hepatis B virus and human blood, bodily fluids, tissues, cells/cell lines that are not genetically modified are still regulated by the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens and have additional Biosafety Level guidance in Centers for Disease Control (CDC)/NIH's Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th edition (2020)

For context, deletions from the NIH Guidelines that are not in the new biosafety policy or perhaps will be provided in guidance documents:

- Some experiments in Section III-C – Experiments involving human gene transfer
- Providing a set of experiments for which the Principal Investigator can notify the IBC simultaneous with initiation
- Exemptions for low risk host-vector systems (*E. coli* K-12, *Saccharomyces, Kluyveromyces, Bacillus subtilis, Bacillus licheniformis*)
- Exemptions for some activities involving transgenic rodents: purchase, transfer, generation of the majority of Biosafety Level 1 (BSL1) transgenic rodents via breeding
- Appendix G covering work practices, personal protective equipment and facility/physical containment criteria for BSL1, BSL2, BSL3 and BSL4, presume will defer to CDC/NIH's BMBL Biosafety Level criteria
- Appendix K covering large scale (greater than or equal to 10 liters of culture) work practices, personal protective equipment and facility/physical containment criteria also covered in CDC/NIH's BMBL Appendix M – Large-scale biosafety.
- Appendix N covering animals that typically require housing outside of laboratory conditions, e.g. nonhuman primates
- United States Department of Agriculture (USDA) will instead cover genetically modified plants and non-zoonotic livestock pathogens

Draft NIH Biosafety policy for Research Involving Biohazards – section, requirement	Clarify	Revise	Comments
Scope: Research involving biohazards is defined as research involving known or potential risk to human health and any of the following: 1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans; 2. Cells, viruses, or organisms, other than plants, that have been genetically modified; 3. Toxins, prions, and other self-aggregating proteins; or 4. Cells or organisms, other than plants, containing 1, 2, or 3 above.	X	X	1. Biological agents: a. Includes opportunistic human pathogens? b. Includes biological agents that per the literature are pathogenic solely for immunocompromised people? c. Includes cells/cell lines that an institutional risk assessment assigns Biosafety Level 1 as per CDC/NIH's BMBL Appendix H: Working with Human, Non-Human Primate (NHP), and Other Mammalian Cells and Tissues? Examples: i. Mouse cell lines from the American Type Culture Collection (ATCC) that are not known to contain an adventitious human pathogen? ii. Cells derived from food grade sources, i.e. obtained from USDA inspected facilities?

Draft NIH Biosafety policy for Research Involving Biohazards – section, requirement	Clarify	Revise	Comments
Scope: (continued) Research involving biohazards is defined as research involving known or potential risk to human health and any of the following: 1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans; 2. Cells, viruses, or organisms, other than plants, that have been genetically modified; 3. Toxins, prions, and other self-aggregating proteins; or 4. Cells or organisms, other than plants, containing 1, 2, or 3 above.	X	X	2. Cells that have been genetically modified – per the policy definition 'genetic modification' includes stable alterations into the genome by passaging, chemical or radiological means. a. Does this include passaging cells/cell lines? i.e. Masters JR and Stacey GN. Changing medium and passaging cell lines. Nat Protoc. 2007;2(9):2276-84, PMID: 17853884 b. Can the NIH Guidelines Appendix C-1 exemption be incorporated into the new policy? Example: cells immortalized by lentivirus vector or retrovirus vector transduction. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2024) (NIH Guidelines) Appendix C-1 currently provides an exemption from IBC approval for "recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome…that are propagated and maintained in cells in tissue culture…with the exceptions listed in Appendix C-I-A." 3. Toxins – per the policy definition 'a protein or peptide produced by living organisms that causes harm in humans'. For toxins <u>not</u> on the Select Agent list: a. Are there toxins outside a specific LD_{50} range that could be excepted from IBC review and approval if already reviewed by institutional chemical safety personnel? b. Are toxin subunits included, e.g. diphtheria toxin subunit A? 4. Self-aggregating proteins (<u>not</u> prions) – per the policy definition 'misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals' - in vitro research included if no oral, permucosal or percutaneous risk demonstrated in the literature? a. Per the literature transmission of misfolded amyloid, alpha-synuclein or tau is primarily by the intracranial route, an unanticipated route of exposure for laboratory personnel. b. Misfolded alpha-synuclein - understood that there is literature demonstrating a possible gut to vagus nerve misfolded alpha-synuclein transmission route to the central nervous system, i.e. potential oral route. c. Amyloid aggregate literature examples: i. Banerjee G et al. Risk of transmission of amyloid β pathology via transfused blood products. Lancet. 2026 Aug 22;408(10556):753-760 PMID: 42624157 "risks of (blood) transfusion-related transmission of amyloid β pathology are currently undefined" ii. Tjornberg LO et al. Transmissable amyloid. J Intern Med. 2016 Aug;280(2):153-63. PMID: 27002185 "However, healthy (human) subjects without inflammation are not susceptible to AA amyloidosis, in contrast to prionoses, but may become primed and develop the disease at a later time-point."

Draft NIH Biosafety policy for Research Involving Biohazards – section, requirement	Clarify	Revise	Comments
Section III-A Responsibilities of the institution - IBC Functions	X	X	1. Per the policy the IBC must…use the required meeting minutes template. Re: the 'NIH Institutional Biosafety Committee Meeting Minutes Draft Template': a. Please provide a template that adheres to federal digital accessibility requirements (Americans with Disabilities Act Title II Regulations Subpart H – Web and Mobile Accessibility https://www.ada.gov/law-and-regs/regulations/title-ii-2010-regulations/#-35200-requirements-for-web-and-mobile-accessibility) b. Inspections/Ongoing Oversight – separate section vs. including 'last inspected' date in each IBC review? i. Is NIH specifying a laboratory inspection frequency? ii. Is NIH requiring IBCs to approve laboratory inspection results? (Per the template: "Discuss the results of laboratory inspections previously granted conditional approval based on correction of deficiencies discussed at a prior meeting.") 2. Per the policy 'approval should be granted for a period not to exceed three years, at which time a *de novo* registration submission and review is required.' Please keep as 'should'. a. If this were a 'must' this new requirement would increase logistic complexity. For IBC registrations that incorporate an animal protocol for which there is also a federal requirement for *de novo* protocol approval every three years, what happens if the IBC and animal protocol expirations are out of sync? Must they harmonize? Which is more important? b. If this were a 'must' this new requirement would increase administrative burden. i. Per the policy, IBC Functions still include "Periodically reviewing approved research conducted at the institution, to ensure compliance with the conditions established in the IBC approval and with the Policy." Institutions therefore typically perform an annual IBC protocol review with the Principal Investigator (PI) to verify protocol accuracy, a laboratory inspection has verified containment conditions, the personnel list is up-to-date, and personnel have been trained. This review may be performed by a Biological Safety Officer (BSO). ii. Per the policy, IBC Functions will already include measures to ensure IBC protocols remain up to date: "During the approval period, any changes to the approved research that have potential impact on the original biosafety assessment must be reviewed and approved by the IBC, or its delegate, before such research is conducted." iii. A *de novo* review requires that an IBC reviewer (generally a PI who should be focusing on research activities) re-do the meeting minutes template components even if work has not changed. In those cases, i.e. administrative updates only, a briefer format be used in the minutes, e.g. IBC PI name, IBC registration number/institutional tracking number, list of biological agents and the Committee reviewer's name?

Draft NIH Biosafety policy for Research Involving Biohazards – section, requirement	Clarify	Revise	Comments
Section III-A Responsibilities of the institution - IBC Functions (continued)	X	X	2. Per the policy 'approval should be granted for a period not to exceed three years, at which time a *de novo* registration submission and review is required.' (continued) b. If this were a 'must' this new requirement would increase administrative burden. (continued) iv. For administrative flexibility please maintain that an expiration date is optional. Rationale: a) An IBC reserves the right to terminate a protocol for noncompliance at any time. b) PIs that know they may easily resurrect, via IBC notification, a previously-approved IBC experiment they remove from their protocol tend to keep protocol length to actively performed work and/or animal protocol experiments as required by NIH Grants Policy Statement 4.1.1.2. v. If an expiration date will be required, please consider extending to a) 5 years to coincide with R01 grant duration, or b) for experiments that also require an animal protocol to 6 years in order to coincide with animal protocol expiration dates. Per NIH Grants Policy Statement 4.1.1.2. animal protocols must include all work proposed in an NIH grant even if the grant duration (5 years) extends past the animal protocol duration (3 years). 3. Per the policy "Reporting certain incidents to NIH that pose a significant risk to human health, using the required incident reporting template" including "any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approval." a. Please clarify 'maintain IBC approval' – does this mean failure to participate in 'periodic review'? b. For "administrative failures" (from the incident reporting template - Background) specifically "Failure to obtain or maintain IBC approval" (from the incident reporting template Part 2. Incident Information – What was the nature of the incident?) – please allow redaction of the Principal Investigator's name for: i. First-time incidents for Principal Investigators (PIs) who are new to the PI role (e.g. PostDoc receiving first faculty position) whose work will be assigned BSL2 or below and they met BSL requirements prior to seeking IBC approval. Rationale: Principal Investigators who are new to the PI role are still learning many of the administrative requirements that come with the PI role. Their name on an incident report could be of significant concern to them as they may think it could negatively affect their ability to seek NIH funding throughout the rest of their career.

Draft NIH Biosafety policy for Research Involving Biohazards – section, requirement	Clarify	Revise	Comments
Section III-B IBC membership		X	1. Per the policy, a "Biological Safety Officer (BSO) must be appointed when the institution conducts research subject to the Policy i) at BSL-3 or 4, or ii) involving GDMOs", and "(i)f an institution does not designate a BSO, the institution must assign another official to take on these responsibilities." Recommendation – any institution that falls under this policy must designate a BSO, even if that role is part-time. Rationale: this practice will ensure that at least one member of the IBC receives institutional support to attend 'appropriate training regarding laboratory safety and implementation' as per the policy Section III-A Responsibilities of the institution. This could include membership in ABSA International (the Association for Biosafety and Biosecurity) and inclusion in the ABSA International Communities discussion groups.
Section III-C Responsibilities of the Principal Investigator (PI)		X	1. Please include a requirement that the PI must sign the research protocol submitted to the IBC. This will ensure that the PI has reviewed the submission vs. delegated to a PI proxy. The signature may be in any form – wet ink, digital, electronic, email, etc. 2. For flexibility, if a PI proxy may be used to sign the research protocol submitted to the IBC, consider restricting to experiments covered by policy Section IV-3 – Research that requires review and approval before initiation and may be delegated to an individual or subgroup of IBC members.
Section IV Categories of Oversight for Research Based on Risk	X		1. Some research that currently falls under Section III-C of the NIH Guidelines for human research study participants may no longer require IBC review and approval. Will IBC approval still be required for: a. Messenger RNA (mRNA) if not self-amplifying? b. Gene editing methods such as CRISPR RNP (clustered regularly interspaced short palindromic repeats ribonuclear protein), CPE (Circular RNA-mediated Prime Editor) or would the human research study participant be considered a genetically modified organism? c. Adeno-associated virus (AAV) vectors since AAV vectors may integrate as per review article PMID: 35690906 and may shed. 2. Policy Section IV-3 – "Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members": a. For the IBC minutes template section "Readout of any projects approved by delegated review" – is that section meant to be inserted in the multipart 'New IBC Registrations and Amendments for Review' or can it be a separate section of the minutes?

Draft NIH Biosafety policy for Research Involving Biohazards – section, requirement	Clarify	Revise	Comments
Section IV Categories of Oversight for Research Based on Risk (continued)	X		2. Policy Section IV-3 – "Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members": (continued) b. Re: 'Research with genetically modified RG1 biological agents' where RG = Risk Group, will there be exceptions e.g. those previously covered by NIH Guidelines "APPENDIX C. EXEMPTIONS UNDER SECTION III-F-8: low risk host-vector systems (*E. coli* K-12, *Saccharomyces, Kluyveromyces, Bacillus subtilis, Bacillus licheniformis*)? c. Please clarify what 'Research conducted with transgenic organisms at BSL-1/ABSL-1' includes with regard to animals. Is it similar to the 'Animal experiments' table currently published for the NIH Guidelines? https://osp.od.nih.gov/wp-content/uploads/2022/11/Animal_Activities_Table.pdf d. Re: 'transgenic organism research at BSL-1/ABSL-1', are transgenic organisms currently assigned Arthropod Containment Levels (ACLs in CDC/NIH's BMBL Appendix E) included? e.g. *Drosophila, C. elegans*, pea aphids, USDA regulated plant pests e. For 'research with well-characterized cell lines', please define 'well-characterized' - any published in the literature? Tested for anticipated adventitious agents by sending lab?

239. University of Melbourne

I am responding: On behalf of an organization

Name: Matthew Gotch (on behalf of the Office of Research Management and the Pro Vice-Chancellor (Research Infrastructure), the responsible policy official)

Name of Organization: University of Melbourne

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): University of Melbourne maintains a diverse research program as a public university, though academic and professional staff in public health and infectious diseases contributed prominently in this feedback.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see in the attachment the University of Melbourne's formal comment on the new policy, which primarily addresses the appropriateness of scope as our central piece of feedback. We have also compiled some specific points of technical feedback within the form below.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 2. Appropriateness of tiered oversight and calibration to risk

We suggest that risk calibration should consider the characteristics of the actual material or system rather than relying on broad categories alone. Relevant factors include replication competence, attenuation, host range, pseudotyping, whether a viral system is single-cycle, and whether a technology edits genomic DNA or targets RNA without genomic modification. Treating replication-competent HIV, attenuated or single-cycle reporter systems, Cas9 and Cas13 technologies as functionally equivalent would not reflect their materially different risk profiles. Cas13 targets RNA and does not edit genomic DNA; when delivered in replication-incompetent lentiviral vectors, the risk profile differs markedly from DNA editors, yet the Policy does not distinguish these pathways.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates

The templates should support transparency without requiring disclosure that creates privacy, security, biosecurity or confidentiality risks. Mandatory publication of IBC minutes, incident reports, key

personnel contact details or detailed biosafety procedures may expose researchers and facilities, reveal security-sensitive operational information, or disclose confidential and proprietary research.

The incident reporting template should distinguish minor, contained events from significant incidents requiring broader notification. Public reporting without clear thresholds, context and explanation may create unnecessary alarm and obscure the distinction between routine laboratory events and matters presenting a material public health risk.

The templates should permit proportionate reporting, aggregation where appropriate, and redaction of personal information, security-sensitive details, proprietary information and information that could increase biosecurity risk. NIH should also recognise reporting already completed under equivalent domestic schemes and permit it to satisfy corresponding NIH requirements.

6. Other feedback relevant to this resource: 6. Implementation resources and additional guidance

Additional implementation guidance will be essential for foreign institutions, and we ask the NIH to consider:

A foreign-assurance pathway allowing institutions to demonstrate equivalent oversight through domestic regulatory and institutional arrangements.

Clear criteria for determining the relevant institution and legal-entity boundary, including co-located institutes, shared facilities and affiliated entities.

Worked examples covering primary human cells with endogenous or latent infection, replication-competent and attenuated viruses, pseudotyped and single-cycle systems, and DNA-editing compared with RNA-targeting technologies.

An equivalence framework mapping BSL requirements to recognised foreign containment standards, including Australian Physical Containment levels.

Guidance on how NIH requirements interact with existing domestic frameworks such as OGTR, SSBA, biosecurity and workplace safety requirements.

Criteria identifying when NIH approval is required before local IBC review of novel or emerging pathogens, together with expedited pathways for urgent public health research.

A foreign-assurance pathway allowing institutions to demonstrate equivalent oversight through domestic regulatory and institutional arrangements.

Clear incident-reporting thresholds, confidentiality protections and rules for redacting public minutes and reports.

Uploaded File: University-of-Melbourne-Signed-Feedback-Letter-Draft-NIH-Biosafety-Policy-for-Research-Involving-Biohazards.pdf

Description: Formal feedback letter signed by Pro Vice-Chancellor (Research Infrastructure)

16 October 2026

NIH Office of Science Policy
6705 Rockledge Drive, Suite 630, MSC-7985,
Bethesda, MD 20892-7985

Dear NIH Office of Science Policy,

Subject: Response to Request for Information on Draft NIH Biosafety Policy for Research Involving Biohazards

The University of Melbourne appreciates NIH's extensive community engagement in developing the draft policy and acknowledges the comprehensive outreach undertaken through regional listening sessions, engagement with biosafety professional organisations, and consultation with Institutional Biosafety Committees and research institutions. Based on the engagement record published by NIH, the consultation process appears to have focused primarily on stakeholders within the United States.

We therefore welcome the current public consultation as an important opportunity for international institutions to contribute to the development of the policy. The University of Melbourne would like the opportunity to foreground concerns shared with many other research institutions in Australia in relation to the proposed scope of the new policy. In our view, both the proposed entity-wide scope of operation and jurisdictional overlap with pre-existing Australian regulatory regimes will produce significant compliance challenges.

Given the substantial participation of overseas institutions in NIH-funded research, we encourage NIH to give particular consideration to feedback from Australian institutions who are subject to mature biosafety regulatory schemes, and to ensure that the final policy appropriately accommodates institutions operating within these robust local regulatory environments which achieve aligned biosafety objectives.

Scope extends to non-NIH-funded research

The University supports NIH's objective of strengthening biosafety oversight for research supported by NIH funding. However, we are concerned that the draft policy extends beyond NIH-funded research and appears to apply to all research conducted at an institution that receives any NIH funding, regardless of whether the relevant project has any connection to NIH support.

The result of this is that research funded by Australian government agencies, industry sponsors and philanthropic organisations would potentially become subject to NIH governance requirements despite having no funding or scientific connection to NIH.

The comprehensive scope may also have a negative impact on international applicants, due to the potential cost of entity-wide compliance which may discourage Australian institutions from applying for, accepting or continuing NIH-supported research. For institutions with modest NIH funding, these costs may make continued participation untenable.

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We respectfully submit that NIH's interests are most appropriately protected by attaching the Policy requirements to NIH-funded research and research directly connected to NIH-funded activities. Extending the Policy to all institutional research is disproportionate to the funding relationship and risks creating significant duplicative administrative burden without a corresponding improvement in biosafety outcomes (see further details on this under the heading “Overlap with Local Frameworks”).

We encourage the NIH to revise the Policy so that it applies only to NIH-funded research and research that directly supports or is materially linked to NIH-funded activities.

Overlap with local frameworks

The current NIH Guidelines recognise host-country regulatory frameworks and permit overseas research to be conducted under those frameworks where local biosafety practices are reasonably consistent with NIH expectations. This principle does not appear to have been carried forward into the draft policy.

Its omission is significant as, without a mechanism recognising equivalent foreign regulatory controls, institutions operating within mature biosafety frameworks may be required to comply concurrently with overlapping domestic and NIH policy requirements.

Australian universities undertaking biomedical research involving biohazards already operate under comprehensive regulatory and institutional oversight frameworks governed by an interlocking set of federal and state laws, sector regulators and technical standards:

- the Gene Technology Act 2000 and the Office of the Gene Technology Regulator (OGTR) control dealings with genetically modified organisms and related containment and licensing;
- the Biosecurity Act 2015 (Cth) provides national biosecurity measures at borders and for nationally significant pests and diseases;
- the National Health Security Act manages the secure handling of Security Sensitive Biological Agents;
- the Work Health and Safety (WHS) Acts and associated model regulations and Codes of Practice implemented by each state and territory set workplace duties for managing hazardous biological agents, risk assessment, containment, personal protective equipment and waste;
- the AS/NZS 2243 series on laboratory safety (microbiological safety and containment) prescribes containment levels, facility design, decontamination and laboratory practice;
- transport of infectious substances is regulated under the Australian Dangerous Goods Code and aligned UN/IATA dangerous goods rules; and
- institutional oversight is provided by research governance mechanisms such as institutional biosafety committees and human research ethics committees to ensure compliance with statutory and standards-based requirements.

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These frameworks may use different terminology, classifications and administrative mechanisms, but seek to achieve equivalent biosafety outcomes as the draft Policy. We would welcome the opportunity to discuss the Australian framework further and respond to any questions.

Requiring foreign institutions to comply simultaneously with the proposed NIH policy and applicable domestic requirements could create material duplication and administrative burden, including:

- maintaining parallel risk assessment and approval processes;
- adapting institutional governance arrangements to satisfy overlapping oversight requirements;
- duplicative reporting and record-keeping obligations; and
- reconciling differing terminology, classifications and administrative requirements across frameworks.

Though both the proposed Policy and Australia's existing biosafety framework are designed to achieve robust biosafety outcomes, overlaying the two frameworks may create duplication that undermines the Policy's objectives. Requiring institutions to maintain parallel governance, approval and compliance processes would divert resources towards administration, create uncertainty regarding applicable requirements and reduce the agility of internationally collaborative and time-sensitive public health research. These additional burdens are unlikely to be accompanied by a corresponding improvement in biosafety outcomes, particularly where institutions are already operating within mature domestic regulatory and oversight frameworks.

We therefore encourage NIH to establish a proportionate pathway under which foreign institutions may demonstrate reasonably consistent compliance with the NIH policy objectives by operating within their local biosafety laws and frameworks. We consider a model centered on a single, institution-level Foreign Assurance, similar to that adopted by OLAW for animal welfare requirements, to be an appropriate precedent. This would enable appropriate NIH safeguards for escalation and significant incident reporting, while preserving the function of established frameworks at the local level.

Thank you for the opportunity to consult with the NIH and for your consideration of the University’s feedback.

Yours sincerely

[redacted]

Prof. Ivan Marusic
Pro Vice-Chancellor (Research Infrastructure)

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240. QIMR Berghofer

I am responding: On behalf of an organization

Name:

Name of Organization: QIMR Berghofer

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Safety Advisor

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Medical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We support effective biosafety oversight. However, it is unclear why this policy is extending NIH requirements to unrelated, non-NIH-funded research simply because an institute receives NIH funding.

Australian institutions already work under national and state requirements, supported by their own biosafety, biosecurity and research governance processes. Adding NIH requirements to this research would create overlapping obligations and substantial administrative work. Please explain what gaps this policy is intended to address specific to Australian research institutes, and what additional safety benefit it would provide.

At a minimum, please consider limiting mandatory application for overseas institutions to only NIH-funded research. If broader application is retained, institutions should be able to demonstrate how their existing regulatory and governance arrangements meet this new policy's objectives. Please outline how the additional requirements in this proposed policy would address any gaps left by Australia's stringent regulatory and governance arrangements.

Please also clarify what is meant by the "institution":
e.g.
1) how the requirements would apply to subrecipients, collaborators and shared facilities.
2) When do obligations begin and end as NIH funding changes.
3) Institutions need to understand the consequences for their other research before accepting an NIH award.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The level of oversight and detail required should match the risks of the research. Local committees review and approve work within their expertise. Please provide clearer guidance on when NIH review/ approval is also needed.

Section II allows research to proceed under another federal agency's oversight once the required approvals are in place. Please clarify whether this includes regulators outside the United States, and outline what institutions would need to provide for this oversight to be recognized.

Incident reporting should also reflect the risk involved in the incident. Minor paperwork or administrative errors that do not put anyone at risk should be treated differently from failures that could cause exposure or a release of biological material. E.g. For equipment faults, the reporting requirements should consider whether backup systems worked and kept the material safely contained. Would the NIH expect to receive reports on such incidents, even when said incidents occur outside of NIH funded projects.

Please note: Institutions have been, and are still responsible for investigating and improving such incidents. However, reporting biosafety events to the NIH should provide a clear safety benefit beyond the institution's own investigation and corrective actions already being made.

3. Continued utility of Risk Groups: Nil

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Nil

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The templates should clearly explain what information is required while allowing institutions to use their existing formats and refer to records already held.

Meeting minutes outline committee decisions, reasons and approval conditions. They should not need to repeat information already documented in applications, risk assessments, training records and supporting evidence. Copying this information into multiple records adds substantial work and increases the chance of inconsistencies.

Concerns regarding how much information would be made public, particularly for non-NIH-funded research. Detailed minutes and incident reports may contain confidential research, commercially sensitive information, staff health information or details that could affect institute security. Depending on the discussion, removing names may not be sufficient to prevent someone from being identified.

The proposal allows some information to be removed before publication, but clearer guidance is needed on how international institutions can meet their national and state legal requirements and confidentiality obligations. Please consider the addition of creating confidential detailed records, where required.

Please also explain the safety benefit of publishing reports of incidents that do relate directly to NIH funded projects. Mandatory publication to our institutes webpage using the NIH template could make staff less willing to report mistakes or speak openly during investigations.

6. Other feedback relevant to this resource: The proposed requirements would increase a substantial administrative burden across biosafety teams, committees, grant administration and other institutional

services.

Further guidance is needed on:

• What evidence is required for a Biosafety Assurance and when NIH may request more information.
• Will existing overseas regulatory approvals, committee arrangements and institutional records be accepted.
• Which non-NIH-funded projects would be considered relevant to this policy, and how long will the obligations to report to the NIH continue for.
• Additional examples of incidents that must be reported to NIH under this policy.
• What information must be published and how privacy, confidentiality and security will be protected.

Description: Nil

241. American Psychiatric Association

I am responding: On behalf of an organization

Name: Brooke Trainum

Name of Organization: American Psychiatric Association

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Policy director

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The American Psychiatric Association (APA) recommends that NIH make clear how institutions should assess requests to use service animals in laboratory settings, so that the policy supports both safety and access for researchers and trainees with disabilities. In September 2025, APA and American Psychological Association Services, Inc. asked the Centers for Disease Control and Prevention (CDC) to clarify language in Biosafety in Microbiological and Biomedical Laboratories (BMBL) stating that animals not associated with laboratory work are not permitted. We explained that treating this language as a categorical prohibition can exclude people who use trained service dogs, including people with psychiatric disabilities, from required coursework, research training, and scientific careers. We urged an individualized assessment of whether a service dog can be accommodated safely in the particular setting.
We appreciate the subsequent clarification issued jointly by CDC and NIH. It explains that the BMBL is advisory, does not address every situation involving service animals, and should not be used as a basis to deny reasonable accommodation. It also encourages institutions to conduct their own risk assessments in compliance with applicable law. This clarification is especially relevant to the proposed NIH policy, which identifies the BMBL as a primary handbook for risk assessment and would establish requirements for institutions receiving NIH funding.
APA recommends that NIH include the following principle in the final policy or accompanying implementation guidance: Institutions should evaluate requests involving service animals in laboratory

settings through an individualized assessment of the proposed activities, facility, potential exposures, and available risk mitigation measures, in coordination with appropriate biosafety and disability accommodation personnel. The BMBL's general guidance concerning animals not associated with laboratory work should not be applied as a categorical basis to deny a service animal accommodation. NIH should also incorporate this principle into training for institutional biosafety committees, biological safety officers, principal investigators, and other personnel who implement the policy. Practical guidance could address how to document the assessment, coordinate the accommodation and biosafety processes, consider measures tailored to the specific space and procedures, and revisit a decision if the research activities change.

242. Daniel Kiss

I am responding: On behalf of myself

Name: Daniel Kiss

Name of Organization: not applicable

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: major concern is that this new policy will enshrine an incorrect (and dangerous) definition of genetic modification as official NIH Biosafety policy. This is particularly dangerous for our member's research. I have once again quoted the problematic language below. In the "General Definitions" section, this document defines Genetic Modification as follows:

Genetic modification:
• The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
• Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
• Have the potential for one or more cycles of replication in a cell; or
• Can be transcribed or translated; or
• The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.

All current definitions of genetic modification center on techniques and experiments that caused permanent changes to the genetic material of the host cell or organism, in other words, their genomic DNA (or RNA for select viruses). However, as the highlighted text above shows, this proposed policy change ignores that decades-old scientific consensus. As the new language includes nucleic acids that "Can be transcribed or translated" this policy will incorrectly classify the vast majority of vaccine technologies as Genetic modifications even though no vaccine platform alters the genome of the recipient.

For example, under this definition, all mRNA vaccines (whose sole function is to be translated into antigen protein that trains the immune system), all virally-vectored vaccines (like the Oxford-AstraZeneca COVID-19 vaccine that has been given to ~2 billion people) which are transcribed into mRNA and then translated into the antigen, and selected live virus and virus-like particle vaccines will deemed genetic

modifications as per official NIH policy. Simply put, including the “Can be transcribed or translated” language as genetically modified is both scientifically wrong and irresponsible.

The confusion that would occur if NIH adopted this factually incorrect definition of genetic modification is a grave concern. For example, the dangers to public health and public trust by this inaccurate definition are enormous. It is easy to envision how anti-vaccine organizations can use this scientifically incorrect definition (which will become official NIH Biosafety policy) to push regulators and policymakers to weaponize the policy and its enforcement mechanisms. Even if anti-vaccine activists don’t attack companies, research institutions, or universities, they will certainly use the new official NIH policy to falsely claim that vaccines are genetically modifying patients. As such, this policy change could be used to further discredit the biotechnology sector, science, and scientists amongst the general public.

The “Can be transcribed or translated” language must be removed from the definition.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): This policy draft would force instant reorganizations within many institutions and would be difficult to enact.

Furthermore, by stating that a biosafety officer is required, but giving no credentials that need to be met for a person to serve in that role, this policy invites confusion

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The requirement of public-facing reports for any and all violations (even administrative ones) within 24 hours is overly burdensome and does nothing to increase the safety or rigor with which the research is conducted.

6. Other feedback relevant to this resource: N/A

Uploaded File: Expression-of-Concern_NIH.pdf

Description: My two largest concerns are spelled out

October 8, 2026

Dear NIH Leadership,

I'm writing to express my deep concern regarding NOT-OD-26-112, which is the Draft NIH Biosafety Policy for Research Involving Biohazards and is intended to replace the NIH's existing guidelines governing recombinant DNA research. I have many concerns regarding the new draft biosafety policy, but since space is limited, I will focus (and quote) two of the most troubling changes below.

As I am a researcher based in an academic research institution, this draft policy would impact me, my research, and our institution. Furthermore, the enforcement mechanism outlined in the new policy could apply to everyone receiving NIH funds -and would also reach into small businesses that are doing sponsored research at NIH fund receiving institutions. My central concern is that the proposed policies, as currently written, could easily be used to curtail vital research, confuse the general public, lead to further mistrust of science, and ultimately harm many institutions that conduct leading edge biomedical research. As the risk of potential damage to the scientific enterprise and many different institutions and companies is large, I'm writing to make sure that changes are made to the NIH's proposed Draft NIH Biosafety Policy for Research Involving Biohazards.

My first concern is that this 15 page policy statement overly simplifies the previous guidelines (which were 132 pages) by eliminating key examples and more explicit guidance regarding certain types of research. These changes open broad gaps in understanding where continuing certain experiments that have been considered standard practice for decades could be construed as (and possibly enforced as) policy non-compliance. That vagueness coupled with the enforcement language (quoted below) creates substantial risks to any institution that receives NIH funding.

> **Compliance and Enforcement**
>
> All institutions conducting NIH-supported research will be required to comply with this Policy, which will be included in the applicable terms and conditions of the award or agreement and included in applicable NIH intramural policies and procedures. As a term and condition for NIH funding, institutions shall ensure that any research conducted at or sponsored by the institution, irrespective of the sourc e of funding, shall comply with this Policy, as specified in applicable terms and conditions of the award or agreement.
>
> Failure to comply may provide a basis for enforcement actions, including, but not limited to, additional special terms and conditions, or termination, consistent with applicable grant regulations; applicable NIH policies and procedures, including NIH intramural policies and procedures; the Federal Acquisition Regulations; and/or other authorities, as appropriate. Enforcement actions may affect future funding decisions for the recipient institution, as authorized in the NIH Grants Policy Statement (GPS).

(All highlights and emphasis marks are mine)

The language above can be interpreted to threaten all NIH funding -both current and future- to an institution for actions deemed to violate the policy. That enforcement clause could be coupled with the policy's vague language to withhold research funds from institutions across the country. The policy requires that every incident report be posted on a public-facing institutional webpage for a minimum of five years, on NIH templates within 24 hours of the incident. Note, that the twenty-four hour reporting list includes administrative lapses such as failure to maintain IBC approval. So, an expired registration becomes a same-day federal report that is then posted publicly with NIH's response attached. In other instances, these public-facing incident reports could further erode trust between research institutions and their communities. Simply, if every infraction, no matter how minor an administrative lapse, must be reported publicly, then it's not hard to envision how opponents of scientific research can use those reports to claim that the community was placed at risk due to 'biosafety violations.'

My second major concern is that this new policy will enshrine an incorrect (and dangerous) definition of genetic modification as official NIH Biosafety policy. This is particularly dangerous for my research. I have once again quoted the problematic language below:

> **General Definitions**
>
> The following terms, which are used throughout the NIH Biosafety Policy, are defined as follows:
> … The first five definitions have been skipped …
>
> ***Genetic modification:***
>
> - The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
>
> - Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
> - Have the potential for one or more cycles of replication in a cell; or
> - Can be transcribed or translated; or
>
> - The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.

(All highlights and emphasis marks above are mine)

All current definitions of genetic modification center on techniques and experiments that caused permanent changes to the genetic material of the host cell or organism, in other words, their genomic DNA (or RNA for select viruses). However, as the highlighted text above shows, this proposed policy change ignores that decades-old scientific consensus. As the new language includes nucleic acids that "Can be transcribed or translated" this policy will incorrectly classify the vast majority of vaccine technologies as ***Genetic modification*** even though no vaccine platform alters the genome of the recipient.

For example, under this definition, all mRNA vaccines (whose sole function is to be **translated** into antigen protein that trains the immune system), all virally-vectored DNA vaccines (like the Oxford-

AstraZeneca COVID-19 vaccine that has been given to ~2 billion people) which are **transcribed** into mRNA and then **translated** into the antigen, and selected live virus and virus-like particle vaccines will deemed genetic modifications as per official NIH policy. Simply put, including the "**Can be transcribed or translated**" language as genetically modified is both scientifically wrong and irresponsible.

The confusion that would occur if NIH adopted this factually incorrect definition of genetic modification is a grave concern. For example, the dangers to public health and public trust by this inaccurate definition are enormous. It is easy to envision how anti-vaccine organizations can use this scientifically incorrect definition (which will become ***official NIH Biosafety policy***) to push regulators and policymakers to weaponize the policy and its enforcement mechanisms. Even if anti-vaccine activists don't attack companies, research institutions, or universities, they will certainly use this factually incorrect definition of genetic modification contained in this draft policy to falsely claim that vaccines are genetically modifying patients. As such, this dangerous definition of genetic modification could be used to further discredit the biotechnology sector, science, and scientists amongst the general public.

The simplest solution is to remove the "**Can be transcribed or translated**" bullet point from the definition of genetic modification.

Because the stakes are so high, I respectfully ask that NIH deliberate on this Draft NIH Biosafety Policy for Research Involving Biohazards and work to ensure that changes are made to this dangerous policy proposal.

Respectfully,



Daniel L. Kiss, PhD.

243. Penn State University

I am responding: On behalf of an organization

Name: Sepideh Sefidvash-Hockley

Name of Organization: Penn State University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: To successfully transition from a recombinant DNA framework to a broader biohazard policy, the NIH must establish clear jurisdictional boundaries. Currently, the draft leans heavily toward human health hazards, leaving the oversight of animal, agricultural, plant, and environmental hazards ambiguous. For example, the rationale for removing genetically modified plants from the main framework is unclear and raises questions about where oversight for agricultural and ecological risks will reside.

Furthermore, foundational definitions require immediate clarification to prevent inconsistent institutional interpretations. The NIH must clearly define what constitutes "genetic modification" (e.g., does it include conventional mutagenesis or passaging?) and provide concrete examples of covered versus exempt activities. Similarly, the definition of "periodic oversight" must be specified to prevent institutions from building overly burdensome, non-standardized compliance systems. Finally, the NIH must explicitly define institutional applicability, detailing how the policy applies to affiliated hospitals, subcontractors, and projects funded by non-NIH sources at NIH-funded institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): We strongly support the introduction of delegated review for lower-risk work and the separation of Risk Group (RG) from Biosafety Level (BSL). However, these flexibilities require clear competency standards. The NIH must define the specific qualifications required for an IBC member to serve as a delegated reviewer and clarify the qualifications required for a Biological Safety Officer (BSO), distinguishing between the administrative assignment of the role and actual technical competency.

Additionally, the NIH must assess the cumulative workload of this "risk-based" system. Requirements for periodic oversight, de novo reviews every three years, expanded scope, and the new Biosafety Assurance could drastically increase administrative burden. Furthermore, the implications of the new Biosafety Assurance—specifically regarding institutional liability and the consequences of NIH suspension—must be thoroughly explained.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed confidential national near-miss system is one of the strongest elements of the draft, but its success depends on separating voluntary learning from punitive enforcement. To protect safety culture, the NIH must define "incident" much more precisely. The reporting trigger must be based on actual or reasonably foreseeable biological risk, distinguishing true exposures and containment failures from minor procedural deviations or basic first aid events.

Furthermore, we urge the NIH to reconsider the mandatory public posting of all final incident reports and standardized IBC minutes. While transparency is important, mandatory public disclosure of lower-level events may discourage candid reporting, encourage defensive classification of incidents, and inadvertently expose proprietary or security-sensitive facility vulnerabilities. A balance must be reached between accessibility of reporting and over publicizing where biohazardous materials are used and located.

6. Other feedback relevant to this resource: Institutions are currently navigating a complex web of federal biosafety regulations. To avoid duplicative risk assessments, the NIH should provide a formal crosswalk aligning this new policy with the USG Policy for Stopping High-Risk Life Sciences Research, the Federal Select Agent Program (FSAP), CDC, OSHA, FDA, USDA, and BMBL guidelines.

Finally, the transition plan will dictate whether implementation is manageable or chaotic. The NIH must explain how existing IBC registrations will be grandfathered, when active protocols require de novo review under the new categories, and what the transition period will be before enforcement of the Biosafety Assurance begins.

Uploaded File: PSU-Comments-on-NIH-Draft-Biohazards-Policy_submitted-10-16-26.doc

Description: Penn State Response to Request for Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards - NOT-OD-26-112

PennState

Office for Research Protections
Senior Vice President for Research
The Pennsylvania State University

814-865-1775
orp@psu.edu
researchsupport.psu.edu/orp

October 16, 2026

Submitted electronically to: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

National Institutes of Health
Office of Science Policy

RE: Response to Request for Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards - NOT-OD-26-112

To Whom It May Concern:

Executive Summary

We support the NIH's goal of replacing a technology-specific recombinant-DNA framework with a more modern, risk-based biosafety system. The draft contains several promising approaches, particularly tiered review, delegated review of lower-risk activities, experiment-specific containment decisions, and national learning from near misses. However, the policy needs substantially greater clarity regarding scope and definitions, delegated-review competency, clinical nucleic-acid research, incident thresholds and public disclosure, institutional assurances, and coordination with other federal oversight systems. A risk-based policy should reduce unnecessary review while ensuring that scarce biosafety expertise remains focused on the activities capable of causing the greatest harm. Penn State supports the comments submitted by COGR and offers the following:

1. Scope, Definitions, and Applicability

To successfully transition from a recombinant DNA framework to a broader biohazard policy, the NIH must establish clear jurisdictional boundaries. Currently, the draft leans heavily toward human health hazards, leaving the oversight of animal, agricultural, plant, and environmental hazards ambiguous. For example, the rationale for removing genetically modified plants from the main framework is unclear and raises questions about where oversight for agricultural and ecological risks will reside.

Furthermore, foundational definitions require immediate clarification to prevent inconsistent institutional interpretations. The NIH must clearly define what constitutes "genetic modification" (e.g., does it include conventional mutagenesis or passaging?) and provide concrete examples of covered versus exempt activities. Similarly, the definition of

"periodic oversight" must be specified to prevent institutions from building overly burdensome, non-standardized compliance systems. Finally, the NIH must explicitly define institutional applicability, detailing how the policy applies to affiliated hospitals, subcontractors, and projects funded by non-NIH sources at NIH-funded institutions.

2. Clinical Research and Gene Transfer
The reorganization of the Human Gene Transfer (HGT) framework creates significant uncertainty for clinical research. The NIH should provide a formal crosswalk demonstrating how research currently reviewed under HGT provisions maps to the new categories. Specifically, the policy must explicitly address the status of conventional, non-replicating, non-integrating mRNA products (such as mRNA vaccines). Because these products do not neatly fit the new clinical triggers involving shedding, integration, or higher-risk administration, the NIH must clarify whether they require IBC review or are exempt.

3. Review Processes, Competency, and Administrative Burden
We strongly support the introduction of delegated review for lower-risk work and the separation of Risk Group (RG) from Biosafety Level (BSL). However, these flexibilities require clear competency standards. The NIH must define the specific qualifications required for an IBC member to serve as a delegated reviewer and clarify the qualifications required for a Biological Safety Officer (BSO), distinguishing between the administrative assignment of the role and actual technical competency.

Additionally, the NIH must assess the cumulative workload of this "risk-based" system. Requirements for periodic oversight, de novo reviews every three years, expanded scope, and the new Biosafety Assurance could drastically increase administrative burden. Furthermore, the implications of the new Biosafety Assurance—specifically regarding institutional liability and the consequences of NIH suspension—must be thoroughly explained.

4. Fostering a Just Safety Culture: Incident Reporting and Transparency
The proposed confidential national near-miss system is one of the strongest elements of the draft, but its success depends on separating voluntary learning from punitive enforcement. To protect safety culture, the NIH must define "incident" much more precisely. The reporting trigger must be based on actual or reasonably foreseeable biological risk, distinguishing true exposures and containment failures from minor procedural deviations or basic first aid events.

Furthermore, we urge the NIH to reconsider the mandatory public posting of all final incident reports and standardized IBC minutes. While transparency is important, mandatory public disclosure of lower-level events may discourage candid reporting, encourage defensive classification of incidents, and inadvertently expose proprietary or security-sensitive facility vulnerabilities. A balance must be reached between accessibility of reporting and over publicizing where biohazardous materials are used and located.

5. Interagency Coordination and Implementation Strategy
Institutions are currently navigating a complex web of federal biosafety regulations. To avoid duplicative risk assessments, the NIH should provide a formal crosswalk aligning this new policy with the USG Policy for Stopping High-Risk Life Sciences Research, the Federal Select Agent Program (FSAP), CDC, OSHA, FDA, USDA, and BMBL guidelines.

Finally, the transition plan will dictate whether implementation is manageable or chaotic. The NIH must explain how existing IBC registrations will be grandfathered, when active protocols require de novo review under the new categories, and what the transition period will be before enforcement of the Biosafety Assurance begins.

Conclusion
We commend the NIH for modernizing this framework and preserving vital flexibilities for local risk assessment. By clarifying definitions, protecting safety culture from punitive public disclosure, and providing clear transitional guidance, the NIH can ensure this policy achieves its goal: concentrating expert attention on significant biological risks rather than expanding administrative compliance structures.

Sincerely,



Sepideh Sefidvash-Hockley
Director of Research Safety and Compliance
Office for Research Protections
Penn State University
sqs71865@psu.edu

244. Jonathan Fidler

I am responding: On behalf of myself

Name: Jonathan Fidler

Name of Organization: Atlanta VA Health Care System

Type of Organization: Government Agency

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Antibiotic resistance

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I strongly encourage NIH to expand upon the list of defined terms in the draft policy. Many mission-critical terms remain undefined. Others have definitions that, in turn, refer to undefined terms.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Whereas I genuinely appreciate the effort to introduce tiered oversight, I strongly encourage NIH to reconsider the use of the terminology "delegated review" as opposed to "designated member review" to harmonize with IACUC and other oversight bodies. Absent of an extremely compelling reason to use differing terminology for a very similar process, this is bound to cause confusion even among subject matter experts. "Designated Member Review" is a much more appropriate term for this process.

3. Continued utility of Risk Groups: Whereas the distinction between RG and BSL can be difficult to explain to those outside of the Biosafety and Biosecurity fields, I do feel it is important to assign risk to agents and containment policy to procedures. I approve of the continued use of Risk Groups.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Guidance will be necessary on reporting of accidents and reporting of meeting minutes if NIH is to expect voluntary compliance. Absent of clear and robust guidance on what may be redacted and what must be included, non-NIH funded institutions may simply feel it is in their best interests to not comply with this policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Requiring standardized templates for both Incident Reporting and Meeting Minutes that will almost certainly differ from those already established at institutions represents significant duplication of administrative effort. I strongly encourage the NIH to reconsider making these forms mandatory, and instead make them optional with included guidelines on what elements are required in Incident Reports and Meeting Minutes should an institution use a different format.

6. Other feedback relevant to this resource: The proposed timeline for implementation is, frankly, not nearly enough time for institutions to pivot their internal policies toward congruency with these

revisions, given how extensively the policy has been revised, as well as legal ramifications and the potential need to hire subject matter experts. One calendar year from roll-out to enforcement will be a bare minimum timeline. Anything less is likely to result in policy noncompliance due to rushed implementation.

245. Christina Pier

I am responding: On behalf of myself

Name: Christina Pier

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Select Agent Responsible Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Select Agent Research Oversight

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH_Comment_Pier.docx

RE: Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

To Whom It May Concern:

I am submitting this comment in response to the National Institutes of Health (NIH) effort to modernize and strengthen the oversight of biosafety. The views and opinions expressed here are my own and do not necessarily reflect the official position of my employer.

In my role as the Select Agent Responsible Official at the University of Wisconsin – Madison, my work to continue to effectively manage a compliant, safe, and secure Select Agent Program will be directly impacted by a new NIH policy on biosafety. I support the comments and recommendations submitted by the Office of the Vice Chancellor for Research (OVCR) and the Institutional Biosafety Committee (IBC) at the University of Wisconsin – Madison as well as comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA) regarding this effort. Collectively these comments appropriately reflect the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs. Additionally, ABSA International — The Association for Biosafety and Biosecurity has provided extensive comments and recommendations from the broader community of biosafety and biosecurity professions that need to be addressed to ensure that this new policy can be implemented effectively by all organizations subject to the new policy.

Several key areas that must be addressed include:

- **Scope and Oversight:** Clarifying which research activities fall under the policy and explicitly addressing when another federal agency oversight substitutes for NIH or IBC oversight under this policy.
- **Institutional Responsibilities:** Ensuring that Institutional Biosafety Committees (IBCs) and biosafety professionals have appropriate authority and institutional support to fulfill expanded responsibilities.
- **Transparency and Incident Reporting:** Balancing public transparency with protection of sensitive research information, individual privacy, and a strong safety culture that encourages reporting of incidents and near misses.
- **Implementation Timeline:** Increasing the proposed six-month effective date to a minimum 12-month or preferably a 24-month phased transition period, accompanied by clear guidance, standardized tools, training, and appropriate resources.

Given the number of unresolved questions and the potential impacts to ongoing research programs, I respectfully request that NIH release revised drafts for an additional period of public review and comment before issuing a finalized policy.

Thank you for the opportunity to comment.

Sincerely,

Christina Pier, MS, RBP (ABSA)
Select Agent Responsible Official
University of Wisconsin - Madison

246. National Institutes of Health, Division of Intramural Research, Animal Research Advisory Committee

I am responding: On behalf of an organization

Name: Dr Mark Hoon

Name of Organization: National Institutes of Health, Division of Intramural Research, Animal Research Advisory Committee

Type of Organization: Government Agency

Role: Government Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): All areas of Biological Research with a primary focus on Biosafety in animal research.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Animal Research Advisory Committee (ARAC) supports NIH's objective of maintaining strong, risk-based biosafety oversight and appreciates the effort to modernize the existing NIH Guidelines. We encourage NIH to ensure that the final policy adjusts oversight of biosafety aspects of animal research to demonstrable biosafety risk while avoiding unnecessary duplication with established animal-care, veterinary, occupational-health, and institutional compliance systems. We offer comments regarding animal-related research, with particular attention to registration, tracking, incident reporting, and administrative burden (see attached document).

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): No Comment.

3. Continued utility of Risk Groups: The current NIH Biosafety Guidelines distinguish between higher-risk animal experiments, BL1 transgenic rodent activities requiring notice, and specified BL1 breeding and purchase/transfer activities that are exempt. The draft Policy suggests that pre-initiation approval for research with transgenic organisms at BSL/ABSL-1 may be required. NIH should consider retaining exemptions or notification-based pathways for well-characterized, low-risk animal activities where the genetic modification does not create a meaningful increase in biosafety risk. In addition, NIH should consider permitting registrations of types of genetic modification of animals rather than requiring a registration for each unique genetic modification. Furthermore, should NIH not want to exempt all BSL/ABSL1 transgenic work from preapproval, we would encourage consideration of whether stratifying risk by the type of genetic modification and by the species to be modified is appropriate, e.g., USDA Animal Welfare Act (covered species) versus not covered species (conventional rodents). We support the proposal for delegated review as a useful streamlining mechanism, but it does not by itself eliminate the extremely burdensome administrative requirement for submission, approval, documentation, and committee reporting (even when streamlined through delegated review) if now exempt activities need to be individually reviewed.

The draft limits IBC approval to three years and requires de novo registration submission and review at the end of that period. For stable, low-risk animal studies and breeding colonies, NIH should consider administrative renewal, continuing review based on changed risk, or a longer approval period when there has been no material change in the biosafety assessment. NIH should also define the types of changes that require prior IBC amendment so routine animal-management changes or minor changes of methods for generation of transgenic animals do not inadvertently trigger unnecessary biosafety review. Provide guidance on amendment and renewal thresholds that would preserve safety while avoiding review of changes with no material biosafety impact.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comment.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft identifies bites, scratches, escapes, and improper disposition involving research at BSL/ABSL-1 or BSL/ABSL-2 as incidents that must be reported to and addressed by the IBC. Many such events are appropriately managed through established animal-care, veterinary, occupational-health, or facility procedures and may have no meaningful biosafety consequence. Indeed, the draft states “Minor spills of low-risk agents, that do not involve a breach of containment and that were properly cleaned and decontaminated, generally do not need to be reported.” which would seem to be equivalent to most of the animal incidents that the draft says should be reported suggesting this requirement would not be appropriate in terms of calibration of risk. Therefore, NIH should consider limiting mandatory IBC reporting to events involving an actual or reasonably possible exposure to a covered biohazard, loss of containment, environmental release, or other material biosafety consequence, while allowing institutions to define pathways for routine events.
The final policy should distinguish between incidents that warrant federal/public transparency and routine lower-risk events that are appropriately documented and reviewed internally. For animal facilities, incident reports may contain operational or facility information requiring careful redaction which would require duplicative burdensome additional documentation. NIH should consider limiting mandatory public posting to NIH-reportable incidents or permitting aggregated and de-identified reporting for lower-risk incidents. At minimum, NIH should issue clear standards for permissible redaction and for protecting security-sensitive, proprietary, personal, and animal-facility information. The final policy should state that institutions may rely on or cross-reference existing IACUC, veterinary, vivarium, occupational-health, select-agent, and other applicable records when those records contain information needed for the biosafety determination. NIH should clarify that the policy does not require a parallel animal inventory, separate animal-level tracking system, or duplicate entry of information already maintained in an existing institutional system unless a distinct biosafety purpose requires it.

6. Other feedback relevant to this resource: NIH should provide feedback identifying the minimum biosafety information required for animal protocols and distinguishing IBC responsibilities from IACUC, veterinary, and animal-facility responsibilities. Where an existing institutional review has already addressed an issue relevant to biosafety, the IBC should be permitted to rely on that review or incorporate it by reference rather than recreate it.

Uploaded File: ARAC-response-to-Biosafety-Policy-Final.docx

The Animal Research Advisory Committee (ARAC) supports NIH's objective of maintaining strong, risk-based biosafety oversight and appreciates the effort to modernize the existing NIH Guidelines. We encourage NIH to ensure that the final policy adjusts oversight of biosafety aspects of animal research to demonstrable biosafety risk while avoiding unnecessary duplication with established animal-care, veterinary, occupational-health, and institutional compliance systems. We offer the following comments regarding animal-related research, with particular attention to registration, tracking, incident reporting, and administrative burden.

1. Preserve proportionate treatment of low-risk transgenic animal activities.

The current NIH Biosafety Guidelines distinguish between higher-risk animal experiments, BL1 transgenic rodent activities requiring notice, and specified BL1 breeding and purchase/transfer activities that are exempt. The draft Policy suggests that pre-initiation approval for research with transgenic organisms at BSL/ABSL-1 may be required. NIH should consider retaining exemptions or notification-based pathways for well-characterized, low-risk animal activities where the genetic modification does not create a meaningful increase in biosafety risk. In addition, NIH should consider permitting registrations of types of genetic modification of animals rather than requiring a registration for each unique genetic modification. Furthermore, should NIH not want to exempt all BSL/ABSL1 transgenic work from preapproval, we would encourage consideration of whether stratifying risk by the type of genetic modification and by the species to be modified is appropriate, e.g., USDA Animal Welfare Act (covered species) versus not covered species (conventional rodents). We support the proposal for delegated review as a useful streamlining mechanism, but it does not *by itself* eliminate the extremely burdensome administrative requirement for submission, approval, documentation, and committee reporting (even when streamlined through delegated review) if now exempt activities need to be individually reviewed.

2. Provide a risk-based alternative to mandatory de novo review every three years.

The draft limits IBC approval to three years and requires *de novo* registration submission and review at the end of that period. For stable, low-risk animal studies and breeding colonies, NIH should consider administrative renewal, continuing review based on changed risk, or a longer approval period when there has been no material change in the biosafety assessment. NIH should also define the types of changes that require prior IBC amendment so routine animal-management changes or minor changes of methods for generation of transgenic animals do not inadvertently trigger unnecessary biosafety review. Provide guidance on amendment and renewal thresholds that would preserve safety while avoiding review of changes with no material biosafety impact.

3. Establish an explicit non-duplication principle for animal records and tracking.

The final policy should state that institutions may rely on or cross-reference existing IACUC, veterinary, vivarium, occupational-health, select-agent, and other applicable records when those records contain information needed for the biosafety determination. NIH should clarify that the policy does not require a parallel animal inventory, separate animal-level tracking system, or duplicate entry of information already maintained in an existing institutional system unless a distinct biosafety purpose requires it.

4. Clarify the division of responsibilities between IBC and animal oversight programs.

NIH should provide feedback identifying the minimum biosafety information required for animal protocols and distinguishing IBC responsibilities from IACUC, veterinary, and animal-facility responsibilities. Where an existing institutional review has already addressed an issue relevant to biosafety, the IBC should be permitted to rely on that review or incorporate it by reference rather than recreate it.

5. Apply a materiality threshold to lower-risk animal incident reporting.

The draft identifies bites, scratches, escapes, and improper disposition involving research at BSL/ABSL-1 or BSL/ABSL-2 as incidents that must be reported to and addressed by the IBC. Many such events are appropriately managed through established animal-care, veterinary, occupational-health, or facility procedures and may have no meaningful biosafety consequence. Indeed, the draft states "Minor spills of low-risk agents, that do not involve a breach of containment and that were properly cleaned and decontaminated, generally do not need to be reported." which would seem to be equivalent to most of the animal incidents that the draft says should be reported suggesting this requirement would not be appropriate in terms of calibration of risk. Therefore, NIH should consider limiting mandatory IBC reporting to events involving an actual or reasonably possible exposure to a covered biohazard, loss of containment, environmental release, or other material biosafety consequence, while allowing institutions to define pathways for routine events.

6. Reconsider mandatory public posting of lower-risk animal incident reports.

The final policy should distinguish between incidents that warrant federal/public transparency and routine lower-risk events that are appropriately documented and reviewed internally. For animal facilities, incident reports may contain operational or facility information requiring careful redaction which would require duplicative burdensome additional documentation. NIH should consider limiting mandatory public posting to NIH-reportable incidents or permitting aggregated and de-identified reporting for lower-risk incidents. At minimum, NIH should issue clear standards for permissible redaction and for protecting security-sensitive, proprietary, personal, and animal-facility information.

Specific Recommendations for the Final Policy

- Preserve or create risk-based exemptions/notification pathways for low-risk transgenic animal breeding, acquisition, transfer, and maintenance where no material biosafety risk is introduced.
- Permit streamlined renewal rather than mandatory de novo review for stable low-risk animal research when the biosafety assessment has not materially changed.
- Define amendment thresholds with examples specific to animal research, including changes in strain, breeding, housing, procedures, vectors, agents, and containment.
- Adopt a single-record/cross-reference principle so existing IACUC, veterinary, vivarium, occupational-health, and other records may satisfy overlapping documentation requirements.
- Clarify that the policy does not independently require a universal animal-level inventory or duplicative animal tracking system.
- Limit mandatory IBC review of routine animal incidents to events with a material biosafety nexus, or allow institutions to use risk-based triage procedures.
- Limit public posting of lower-risk incidents or permit aggregated/de-identified disclosure, with clear redaction standards for sensitive facility and personnel information.
- Provide an IBC-IACUC coordination crosswalk and model workflows before the effective date.
- Provide adequate implementation time, standardized definitions, and burden estimates that specifically account for high-volume animal research programs.

ARAC supports a streamlined modern biosafety framework that directs oversight and institutional resources toward activities presenting meaningful risk. For animal research, the final policy should preserve proportionate pathways for low-risk activities, prevent duplicative registration and tracking, establish clear boundaries between IBC and animal-care oversight, and focus incident review and public reporting on events with a meaningful biosafety nexus. These clarifications would strengthen implementation while allowing institutional biosafety programs to concentrate expertise and resources where they provide the greatest safety benefit.

Source Notes

1. NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (released Aug. 19, 2026; comments due Oct. 19, 2026), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html.
2. NIH, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), especially Sections III-D-4, III-E, III-E-3, III-F and Appendices C-VII, C-VIII, and M, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.
3. NIH Office of Science Policy, Draft Policy Table of Changes (August 2026), https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf. NIH identifies this document as a quick-reference guide rather than a substitute for the draft policy.

247. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosafety

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As a member of ABSA international see Attachment, I am in full agreement with ABSA's interpretation and recommendations for revision and improvement.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: ABSA-NIH-Biosafety-Policy-Comments-Concurrence.pdf

Description: Concurrence with ABSA Recommendations

ABSA International — The Association for Biosafety and Biosecurity

Organization:	ABSA International 1200 Allanson Road, Mundelein, IL 60060 Phone: (866) 425-1365 | Email: info@absa.org | Web: www.absa.org
Date:	October 19, 2026
To:	Office of Science Policy National Institutes of Health 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892
Submission Portal:	Submitted via NIH OSP Electronic Comment Portal
Subject / Notice:	Formal Public Comments and Recommendations on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice Number: NOT-OD-26-112)

ABSA International, the Association for Biosafety and Biosecurity, is a nonprofit professional association representing biosafety and biosecurity professionals in the United States and internationally. Our membership spans academic and research institutions, government laboratories, biotechnology companies, healthcare organizations, public health agencies, and consulting practices. Members bring scientific, technical, operational, and regulatory expertise across diverse biological research and laboratory settings.

ABSA's comments reflect the practical experience of professionals responsible for translating biosafety policy into daily practice. Our members conduct risk assessments, support Institutional Biosafety Committees (IBCs), develop training and containment practices, investigate incidents, and advise institutions on compliance. They understand how policy requirements affect laboratory safety, reporting culture, institutional resources, and the conduct of research.

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public

confidence in NIH-supported science. ABSA supports NIH's efforts to strengthen biosafety oversight. We offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

***Topic to Address**: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:

    a. the nature and stability of the genomic modification;

    b. whether the modification is heritable and the potential for transmission through breeding;

    c. effects on animal health, phenotype, host range, susceptibility, or disease;

    d. potential entry into breeding or food-production systems;

    e. potential environmental release or interaction with non-research animal populations;

    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and

    g. applicable federal, state, or other regulatory oversight.

2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

    Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

ABSA International believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, ABSA International requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, ABSA International welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. ABSA International does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. ABSA International recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, ABSA International recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with ABSA's earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. ABSA International recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, ABSA International kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. ABSA International encourages NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While ABSA supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: ABSA recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

248. Washington University in St. Louis

I am responding: On behalf of an organization

Name:

Name of Organization: Washington University in St. Louis

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Executive Summary

Washington University in St. Louis (WashU) supports NIH's goal of establishing a comprehensive and adaptable biosafety framework that protects research personnel, the public, and the environment while responding to evolving scientific risks. The draft policy provides an important opportunity to strengthen consistency in biosafety oversight across institutions. WashU's principal recommendations are intended to ensure that the final framework remains risk-based, scientifically workable, and feasible to implement without diverting oversight resources from research that presents the greatest biosafety risk.

Across the six areas addressed in this RFI, several themes recur. First, key definitions and scope provisions should clearly distinguish novel, higher-risk, or higher-uncertainty research from routine, well-characterized activities. Second, the level and timing of IBC oversight should remain proportional to actual risk, with appropriate use of exemptions, notification-based pathways, and delegated or expedited review for lower-risk research. Third, Risk Groups should remain a useful baseline for risk assessment without functioning as a fixed proxy for containment when the characteristics of a modified agent or experimental context alter risk.

WashU also recommends that compliance, incident-reporting, and public-transparency requirements reinforce a strong safety culture. Accountability is essential, but enforcement should distinguish significant biosafety failures from administrative deficiencies, and reporting requirements should preserve incentives for candid reporting of near misses and lower-risk events. Finally, successful implementation will require clear transition rules, practical guidance and decision tools, sufficient federal review capacity, and adequate time for institutions to modify systems, training, workflows, and existing protocol portfolios.

These recommendations share a common objective: focusing biosafety oversight and institutional resources where they provide the greatest safety benefit while preserving efficient pathways for well-characterized, lower-risk research.

1. Appropriateness of the scope of the new policy, including the definition of biohazard for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

Discussion: Several elements of the proposed scope are sufficiently broad or undefined that they could

substantially expand IBC oversight of routine, well-characterized, lower-risk research without a corresponding increase in biosafety benefit. Greater specificity is needed to ensure that the scope is calibrated to actual risk and can be implemented consistently across institutions.

The definition of a biological agent as an agent that "causes human disease" would benefit from clarification regarding the population on which that determination is based. Elsewhere in the draft policy, Risk Group classifications are described in relation to effects in a healthy adult, suggesting a potentially narrower standard than the general definition of biological agent. NIH should clarify the intended relationship between these provisions so institutions can determine consistently which agents fall within scope.

The definition of a "novel agent or organism" also requires refinement. The draft identifies chimeras as an example of a novel agent or organism but does not define "chimera." As written, that terminology could encompass common viral vectors and recombinant constructs that are well characterized and routinely used under established biosafety practices. During institutional review, investigators noted that many routinely used gene-therapy and viral-vector systems could technically be described as chimeric. The final policy should distinguish novel or higher-uncertainty constructs from routine recombinant or chimeric systems whose risks are already well understood. NIH should also clarify whether "novel" refers to a truly newly identified biological agent or encompasses newly collected variants or isolates of an otherwise well-characterized agent. Without that distinction, routine environmental or clinical sampling, including isolation of new variants of common pathogens for sequencing or characterization, could be interpreted inconsistently.

The term "wild type" also warrants clarification. In virology, a laboratory reference strain may have undergone passage or adaptation and may not be identical to a primary or clinical isolate. In many fields, "wild type" is also used simply to denote the parental strain from which laboratory clones or mutants are derived, and that parental strain may itself be a long-established, laboratory-adapted isolate. In addition, RNA viruses exist as quasi-species represented by a consensus sequence rather than a single fixed sequence, and mutations introduced experimentally may also occur naturally. Without a scientifically workable definition, institutions and federal reviewers could apply "wild type" inconsistently when determining whether research falls within scope or requires additional review.

Additional clarification is needed regarding research with primary cells that may contain adventitious agents. A broad interpretation could extend IBC review to routine processing of human clinical samples even when the activity is already managed through established bloodborne-pathogen protections. Similarly, the provision covering clinical products capable of shedding, replicating, or integrating could be interpreted to extend beyond genetically modified or vector-based products to other cell-based interventions. NIH should clarify the intended boundaries of these provisions so that the policy does not inadvertently duplicate existing safety oversight or bring activities outside the intended biosafety risk framework into IBC review.

WashU Operational Example: At WashU, some ambulatory and clinical research settings process primary human samples for activities such as aliquoting, preparation for shipping, or clinical trial testing. These activities are currently managed through bloodborne-pathogen training, appropriate PPE, and related safety requirements rather than full IBC review when no known or suspected infectious agent is involved. The draft policy language regarding primary cells that may contain adventitious agents creates uncertainty as to whether these routine activities would newly require IBC protocols, potentially creating duplicative oversight without a clear additional biosafety benefit.

Recommendation: NIH should revise the final policy and accompanying guidance to:

• define key scope terms, including “biological agent,” “novel agent or organism,” “chimera,” and “wild type,” using scientifically meaningful criteria and examples that distinguish higher-risk or higher-uncertainty research from routine, well-characterized activities;
• clarify when primary human cells and clinical sample processing fall within IBC oversight and when existing bloodborne-pathogen or other established safety programs are sufficient;
• clarify the intended scope of the clinical research provisions for products capable of shedding, replicating, or integrating, including their applicability to non-vector cell-based products; and
• provide clear exclusions or examples to prevent routine, low-risk research from being unintentionally captured by the expanded definition of biohazard.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Discussion: WashU supports a tiered oversight framework in which the level of review is calibrated to the biosafety risk and uncertainty associated with the proposed research. The draft policy appropriately recognizes that not all research involving biohazards warrants the same level of oversight. However, several of the proposed categories appear likely to move substantial volumes of routine, lower-risk research from currently streamlined institutional pathways into delegated or full IBC review. Without additional refinement, the framework could increase administrative burden and delay research without a commensurate improvement in biosafety.

The distinction among research requiring NIH and IBC approval, full IBC review, and delegated review is particularly important. Under the proposed framework, initial submissions involving genetically modified cells, viruses, or organisms generally require IBC review and approval before initiation, whereas only specified lower-risk activities may be delegated to an individual or subgroup of IBC members. The delegated-review list includes certain activities such as genetically modified Risk Group 1 agents, BSL-1/ABSL-1 transgenic organisms, replication-incompetent non-integrating vectors expressing low-risk transgenes, and well-characterized cell lines. Although this is a useful starting point, the categories should be sufficiently broad and clearly defined to preserve efficient review of well-characterized, low-risk research.

The need for proportionality is especially apparent for replication-defective or single-cycle agents, routine cloning systems, well-characterized vectors, and other research in which the biological characteristics substantially limit the potential for propagation or harm. During WashU’s review, investigators and biosafety personnel repeatedly emphasized that such work should remain eligible for appropriately streamlined pathways, including exemption, notification-based review, or expedited or delegated review, as warranted by risk, rather than requiring more resource-intensive committee processes.

Risk assessment should also consider the biological context in which a gene or factor is being studied. A factor associated with virulence in its native organism may not create the same hazard when cloned into a non-pathogenic laboratory strain solely for nucleic-acid propagation or protein production. Requiring heightened review based on the label “virulence factor” alone, without considering expression, host context, and experimental use, could unnecessarily delay routine research without improving safety.

The change in timing of review is also significant. Under current WashU practices, some well-characterized, low-risk activities are exempt from formal NIH Guidelines review or may proceed concurrently with institutional notification. Under the proposed framework, these activities would instead require documented prior approval through either delegated or full IBC review. Requiring prior approval for activities whose underlying biosafety risk has not changed may create avoidable delays without providing a corresponding safety benefit.

The proposed treatment of emerging, novel, or zoonotic agents also raises a different tiering concern. The draft policy requires NIH and IBC approval before research may begin when a Risk Group classification or recommended minimum containment level is not available in the BMBL. This approach appropriately recognizes the uncertainty associated with newly identified agents, but it could also create a significant delay in pathogen discovery and public health response if federal review is not sufficiently rapid. During an outbreak, the ability to isolate and characterize a newly identified agent is time-sensitive. A tiered framework should therefore account not only for risk, but also for the consequences of delaying research necessary to characterize that risk.

WashU Operational Example: Under current WashU practices, some well-characterized activities, including certain AAV and ecotropic retroviral vector work, can be handled through streamlined institutional pathways, including exemption or notification-based processes, rather than requiring prior committee approval. The draft framework would require documented prior approval through the IBC or an authorized delegated-review mechanism before such work begins. Similarly, BSL-1/ABSL-1 transgenic animal activities that currently may not require the same level of IBC review would become subject to delegated review under the proposed policy. These changes could substantially increase formal reviewer involvement and introduce additional approval steps even when the underlying risk is low and well understood. This may delay experimental progress and will divert review time from higher-risk work or novel experimental procedures where the IBC's time and expertise will be better spent.

Recommendation: NIH should refine the tiered oversight framework to:

• preserve appropriate exemptions, notification-based pathways, and delegated or expedited review mechanisms for well-characterized, lower-risk research, including clearly defined categories of replication-defective, single-cycle, and other low-risk vector systems;

• provide clear definitions and examples for terms and categories such as "certain vectors," "well-characterized cell lines," and "virulence factors," including how biological context should inform eligibility for delegated review, so that institutions can apply the framework consistently;

• allow institutional IBCs sufficient discretion to determine, based on a documented risk assessment, when a low-risk activity may remain exempt, proceed through notification, or receive expedited or delegated review;

• clarify that de novo review at renewal does not automatically require full committee review and may be completed through delegated review when the research continues to meet appropriate lower-risk criteria;

• clarify the review expectations for BSL-1/ABSL-1 transgenic organisms and other activities that may be newly brought into formal IBC review;

• establish a rapid, predictable federal review process for emerging, novel, or zoonotic agents, particularly when timely research is important to an active public health response; and

• evaluate the cumulative administrative burden created by shifting currently streamlined activities into formal review and ensure that additional oversight is proportionate to the biosafety benefit achieved.

3. Continued utility of Risk Groups: Discussion: WashU supports retaining Risk Groups as a useful starting point for biosafety risk assessment, but RG classification should not function as the sole determinant of the containment level required for a particular experiment. The draft policy appropriately recognizes that RGs and BSLs are related but distinct concepts: RGs describe characteristics of the biological agent, whereas the appropriate BSL depends on the specific research activities, manipulations, genetic modifications, routes of exposure, and available mitigation measures.

This distinction is particularly important when agents are genetically modified. The risk associated with a

modified agent may be greater or lower than that of its parent. Genetic modifications can alter pathogenicity, transmissibility, host range, tissue tropism, or other characteristics that increase risk, but they can also attenuate an agent or render it replication defective. The draft policy itself acknowledges these possibilities and appropriately calls for consideration of both the underlying agent and the effect of the modification.

For this reason, WashU recommends that RG classification remain a baseline input to risk assessment rather than a fixed proxy for laboratory containment. The final determination of BSL should reflect the characteristics of the modified agent and the manner in which it will be used. A framework that relies too heavily on parent-agent RG classification could result in containment requirements that do not reflect the actual risk of a particular construct or experiment.

The usefulness of either RG or BSL classifications also depends on the availability of current, authoritative federal guidance. During WashU's review, investigators and biosafety personnel noted that new and emerging agents may not be reflected promptly in existing reference materials. The draft policy's proposal to publish containment determinations that can be relied upon across institutions could improve consistency and reduce duplicative requests, provided those determinations are updated frequently and made available in a timely manner.

Illustrative Example: A genetically modified agent derived from an RG3 parent may be attenuated or replication-defective in a manner that materially reduces its biological risk. In such a case, automatically equating the parent RG with BSL-3 containment may impose a level of containment that is not supported by the characteristics of the modified construct. Conversely, a modification to a lower-risk agent that increases transmissibility, host range, or pathogenicity could justify higher containment.

These examples illustrate why RG classification is most useful as the starting point for a structured risk assessment, with the final containment determination based on the properties of the specific agent and the proposed experimental manipulations.

Recommendation: NIH should:

• retain Risk Groups as a baseline component of biosafety risk assessment, while making clear that RG classification does not by itself determine the appropriate BSL for a specific experiment;

• preserve a risk-assessment framework that accounts for both risk-increasing and risk-decreasing effects of genetic modification;

• provide clear criteria and examples for circumstances in which the appropriate BSL may reasonably differ from the RG classification of the parent agent;

• maintain a centralized, publicly accessible resource containing NIH-approved containment determinations that institutions may rely upon without submitting duplicative requests; and

• establish a process for frequent and timely updates to RG classifications, BSL recommendations, and containment determinations as new agents and scientific information emerge.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Discussion: WashU supports meaningful accountability for institutional biosafety programs and agrees that effective compliance mechanisms are necessary to protect research personnel, the public, and the environment. At the same time, enforcement should be proportionate to the nature, severity, and consequences of the noncompliance. The draft policy authorizes a range of enforcement actions, including additional terms and conditions, suspension or termination of funding, and potential effects on future funding decisions. Given the breadth of the proposed policy and the number of activities that may newly fall within its scope, NIH should ensure that enforcement distinguishes significant safety failures from inadvertent or administrative noncompliance

that may arise during implementation of a substantially expanded framework. Since the draft policy describes a broad range of enforcement actions, NIH should provide clear guidance or examples of the criteria under which each enforcement action could be taken.

The proposed Biosafety Assurance mechanism may provide a useful means of establishing institutional accountability, but additional guidance is needed regarding the expected content, review process, and standards for NIH approval. The draft policy requires institutions to document lines of authority, publicly available biosafety procedures, IBC information, training, incident reports, and other elements of the institutional program. Greater clarity regarding how NIH will evaluate these Assurances and the required supporting documentation would help institutions understand whether the process is intended primarily as an organizational attestation, a programmatic review, or a more formal assessment of institutional biosafety systems.

Compliance mechanisms should also reinforce, rather than undermine, a strong safety-reporting culture. The draft policy appropriately encourages confidential voluntary reporting of near misses and procedural issues to the National Biosafety Data and Safety Analysis Center and states that NIH will not use voluntarily submitted information for enforcement or funding action when specified conditions are met. This non-punitive framework creates a protected learning system that supports continuous improvement and should be preserved. At the same time, the broader public-reporting requirements elsewhere in the policy could create tension with that goal if researchers become reluctant to report minor events or near misses because of concerns about public disclosure.

For research and institutions not subject to the policy, voluntary adoption may be more effectively encouraged through clear, practical, and scalable standards, training resources, shared best practices, and demonstrated biosafety benefit than through mechanisms that resemble indirect enforcement. A policy designed to serve as a model framework should therefore be sufficiently clear, risk-proportionate, and practical so that institutions can adopt its principles without assuming unnecessary administrative burden.

Illustrative Example: A newly expanded policy may result in institutions identifying activities that were previously handled through streamlined or alternative safety processes but that now require formal IBC review or documentation. Failure to complete a newly required administrative step should not automatically be treated in the same manner as conduct that creates a significant biosafety risk, such as knowingly conducting high-risk research without required approval or failing to respond appropriately to a serious containment event.

Similarly, a researcher who voluntarily reports a near miss provides information that may help prevent a future incident. Compliance structures should encourage that behavior rather than disincentivize the reporting of low-level events that can provide important lessons for institutional safety programs.

Recommendation: NIH should:

• apply compliance and enforcement mechanisms proportionately, taking into account the severity, duration, intent, and actual or potential biosafety consequences of noncompliance;

• distinguish significant safety violations from administrative or procedural deficiencies, particularly during implementation of the new policy;

• provide clear guidance on the Biosafety Assurance process, including the standards NIH will use to review and approve institutional Assurances;

• preserve strong protections for voluntary near miss and safety-learning reports so that institutions and investigators are encouraged to identify and address problems before they result in harm;

• align public-reporting and enforcement requirements with the goal of maintaining a candid

institutional safety culture; and
• encourage voluntary adoption by non-covered institutions through practical guidance, training, model procedures, and other implementation resources that demonstrate the value of the framework.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Discussion: WashU supports transparent biosafety oversight and consistent documentation of significant incidents. Use of the proposed IBC meeting minute template appears generally workable and the requirement to publicly post IBC meeting minutes is consistent with WashU's existing practices. Of significant concern, however, is the proposed incident-reporting framework, particularly the requirement to publicly post incident reports and the relationship between reportable incidents, lower-risk events reviewed by the IBC, and broader institutional safety-learning activities.
The draft policy distinguishes incidents that require notification to NIH from certain lower-risk incidents that must be reported to and reviewed by the IBC but do not require NIH notification. It also requires institutions to post incident reports on a public-facing website after institutional or NIH review. Greater clarity is needed regarding exactly which reports must be publicly posted and the level of information that must be included.
WashU is particularly concerned about the potential negative effect of mandatory public disclosure on a strong safety-reporting culture. Effective biosafety programs depend on investigators and laboratory personnel reporting not only serious events, but also minor incidents and near misses that provide opportunities for learning and prevention. If lower-level events automatically require public disclosure, researchers may become less willing to report them candidly. This could undermine the preventive purpose of institutional incident review.
The incident-reporting template should therefore distinguish transparency related to significant biosafety events from institutional systems designed for continuous improvement. Publicly posted information should also be understandable in context. Highly technical reports may be difficult for a general audience to interpret and could create misunderstanding without necessarily advancing biosafety. NIH should consider whether a contextualized or lay summary could satisfy public-transparency objectives while the detailed technical report remains available to NIH and appropriate institutional oversight bodies.
Clear guidance on allowable redactions will also be important. Incident reports and meeting minutes may include information about research protocols, animal models, facilities, or other details for which public disclosure could raise privacy, security, legal, intellectual property, or research-sensitivity concerns. Even when investigator names and specific locations are omitted, combinations of scientific, protocol, or facility information may make it possible to infer the laboratory or investigator involved. The final templates should provide consistent standards for what institutions may redact, summarize, or otherwise limit while still meeting NIH's transparency expectations.
An alternative approach would be for NIH to provide public transparency through a centralized, nationally aggregated reporting system rather than requiring institutions to post detailed incident reports locally. Aggregated reporting by incident risk tier, containment level, or other non-identifying characteristics could support transparency and national biosafety learning while reducing the likelihood that technical details can be traced back to individual investigators or laboratories.
WashU Operational Example: WashU currently encourages broad internal discussion of laboratory incidents so that the IBC and Environmental Health and Safety personnel can identify trends, share lessons learned, and improve safety practices. This can include minor laboratory events that may not ultimately constitute an NIH-reportable biosafety incident. The value of this approach is that relatively

minor events can identify weaknesses in procedures or equipment before a more consequential event occurs.
Over the past 12 months, WashU submitted 12 reportable incidents to NIH Office of Science Policy. Based on recent institutional experience, if all lower-risk incidents were reportable under the proposed framework, WashU estimates approximately 12 additional reportable incidents annually. Although an additional incident report per month would be operationally manageable, the requirement to publicly disclose these lower-risk incidents could discourage candid reporting without providing a commensurate biosafety benefit.
Consequently, the WashU IBC could expect to see a reduction in what is formally brought before the IBC, limiting opportunities for important safety-learning discussions and inadvertently weakening an existing mechanism for preventative learning.
WashU also currently redacts certain animal-related details from publicly available IBC minutes to avoid inadvertently identifying sensitive research activities. Clear federal standards regarding permissible redactions would help institutions maintain appropriate transparency without creating unintended disclosure risks.
Recommendation: NIH should:
• create policy requirements that clearly distinguish between incidents requiring NIH reporting, lower-risk incidents requiring IBC review, and voluntary institutional near miss or safety-learning reports;
• specify which categories of incident reports must be publicly posted and whether all lower-risk incidents reviewed by an IBC are intended to trigger public disclosure;
• preserve the ability of institutions to maintain broader internal incident and near miss reporting systems without automatically requiring conversion of those reports into publicly posted records;
• provide clear and consistent standards for allowable redactions and summarization in both incident reports and IBC meeting minutes, including information related to research protocols, animal models, facilities, personnel, privacy, security, and other details that could inadvertently identify sensitive research activities;
• consider a centralized, nationally aggregated public reporting approach that provides meaningful information about biosafety incidents and trends without requiring publication of locally identifiable technical details;
• consider permitting a contextualized or lay summary for public posting while detailed technical incident information is provided to NIH and retained by institutional oversight programs; and
• ensure that the meeting minute and incident-reporting templates capture information necessary for accountability without requiring duplicative documentation or discouraging candid safety reporting.

6. Other feedback relevant to this resource: Discussion: WashU agrees that detailed implementation resources will be essential to successful adoption of the proposed policy. The draft policy would significantly change the scope of research subject to biosafety oversight, the categories and timing of IBC review, institutional assurance requirements, protocol approval periods, public-posting obligations, and federal review processes. NIH proposes an effective date six months after publication of the final policy and would apply the policy to existing awards and ongoing research as of that date. Institutions will therefore need sufficient guidance well in advance of implementation to revise policies, information systems, training materials, IBC workflows, public-facing websites, and protocol-review processes. Transition guidance is particularly important for research already approved when the policy becomes effective. WashU currently operates on a five-year IBC approval cycle, whereas the draft policy limits IBC approvals to three years and requires a de novo registration submission and review at renewal. NIH

should clarify whether existing institutional approvals may remain in effect until their currently scheduled expiration dates and transition to the new framework at their current renewal date, or whether they must be converted or re-reviewed when the policy becomes effective. NIH should also clarify whether the required de novo review at renewal may be completed through delegated review when warranted by risk, or whether renewal automatically requires full committee review. This distinction has substantial implications for institutional feasibility and committee capacity. Similar clarity is needed for previously reviewed agents and constructs, including previously deselected or otherwise federally characterized strains, so that institutions do not repeat reviews solely because the policy framework has changed. Requiring broad re-review within the six-month implementation period could create a substantial concentrated workload without a corresponding biosafety benefit.

Additional guidance is also needed on the proposed Biosafety Assurance. The draft describes the Assurance as documentation submitted through the Authorized Organizational Representative and approved by NIH for up to four years, but the process and approval criteria are not fully described. NIH should clarify whether the Assurance is intended primarily as an institutional attestation or a more substantive programmatic review; what documentation NIH will evaluate; the respective responsibilities of the AOR, IBC, Biological Safety Officer, and other institutional units; the renewal process; and any pre-award coordination expected between institutional signing officials and biosafety programs.

The requirement for periodic review of approved research also warrants implementation guidance. NIH should clarify whether existing institutional laboratory-inspection or Environmental Health and Safety audit processes may satisfy this requirement when appropriately designed, or whether the policy contemplates a separate IBC post-approval monitoring program.

Guidance is similarly needed regarding research subject to oversight by another federal agency. The draft policy states that research under the regulation or purview of another federal agency may proceed under that agency's oversight once applicable approvals have been obtained. NIH should explain how institutions should document such reliance and whether continuing IBC review of amendments, renewals, or other changes is expected for research subject to another agency's oversight, such as FDA-regulated clinical trials.

Finally, implementation resources should provide practical definitions, decision tools, and examples for provisions that may otherwise be interpreted differently across institutions. Priority areas include which vectors qualify for delegated review; the meaning of "well-characterized cell line"; treatment of BSL-1/ABSL-1 transgenic organisms; when primary clinical samples require IBC review; application of the clinical research provisions to cell-based products, probiotics, and similar interventions; and the treatment of previously reviewed, commonly used agents and constructs. These questions emerged repeatedly during WashU's review of the draft policy.

WashU Operational Example: WashU currently uses a five-year IBC approval cycle and maintains 767 active IBC protocols, including 720 pre-clinical and 47 clinical protocols. If existing approvals are permitted to transition through their normal renewal dates, implementation can be phased over time as protocols enter the new three-year de novo review cycle. By contrast, requiring existing protocols to be converted or re-reviewed during the six-month implementation period would concentrate substantial review activity at the same time WashU is revising procedures and information systems, training investigators and reviewers, implementing new review categories, and establishing the Biosafety Assurance process. Clear grandfathering and transition rules would allow institutions to distribute this work according to existing approval dates rather than creating a concentrated administrative burden that does not itself improve biosafety.

Recommendation: NIH should:
• publish final implementation resources sufficiently in advance of the effective date to permit institutions to develop and test the systems, procedures, training, and workflows necessary for compliance;
• establish clear transition and grandfathering rules for existing protocols and approvals, previously reviewed agents and constructs, and previously deselected or otherwise federally characterized strains, including guidance for how current approval periods should transition to the proposed three-year de novo review cycle;
• allow existing protocols to transition through normal renewal cycles when feasible rather than requiring wholesale re-review during the implementation period, and consider lengthening the six-month implementation period if substantial re-review or conversion will be required;
• clarify that de novo renewal review may use delegated review pathways when appropriate based on the risk and characteristics of the continuing research;
• provide detailed instructions for the Biosafety Assurance process, including required documentation, NIH review criteria, renewal procedures, institutional roles, and any pre-award requirements;
• clarify what constitutes adequate periodic review of approved research and when existing institutional inspection or monitoring programs may satisfy that responsibility;
• explain how institutions should implement and document reliance on oversight provided by another federal agency;
• issue definitions, decision tools, FAQs, and practical examples addressing common research activities and ambiguous review categories so that the policy is interpreted consistently across institutions;
• maintain a current, searchable federal resource containing RG classifications and containment determinations that can be relied upon across institutions;
• assess the cumulative implementation burden of the proposed framework and provide practical, scalable resources that support institutions with differing levels of biosafety infrastructure and administrative capacity; and
• ensure that federal review processes and capacity do not create unnecessary research bottlenecks or delays, particularly when institutional action depends on NIH classification or containment guidance.

249. Roswell Park Comprehensive Cancer Center

I am responding: On behalf of an organization

Name: Irwin Gelman, PhD

Name of Organization: Roswell Park Comprehensive Cancer Center

Type of Organization: Healthcare Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer/Oncology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): We agree that risks involving accidents that subject workers to known or potentially infectious agents should be included on our public-facing institutional website. These would be consistent with what were previously referred to as “significant problems, violations or significant research-related accidents and illnesses”. In contrast, we believe that lower risk incidences and accidents should be reported to the Institution only. These include cases where no infectious agents are involved, such as non-skin-breaking mouse scratches or bites, or cuts from glass. Such issues are dealt with internally by our institution’s Occupational Health and Safety Office and not by Biosafety. As these incidents are not significant and do not require NIH notification they should not require public notification.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We propose that meeting minutes should continue to use any format routinely used by the Institute if it includes all the necessary information NIH deems necessary to relay the review process that was performed.
If the draft of the proposed meeting minutes template is ultimately chosen, here are some comments:
i) It would be burdensome to list each IBC member’s title in the minutes, especially because those are already posted on the online committee roster.
ii) Similarly, it would be redundant and cumbersome to document the training certification for each application’s personnel in the meeting minutes; these certifications are validated at the submission of each protocol, and personnel lacking complete training are not allowed to be listed when the application is reviewed at the monthly IBC meeting.

6. Other feedback relevant to this resource: N/A

250. New York University & Langone Medical Center

I am responding: On behalf of an organization

Name: IBC Director

Name of Organization: New York University & Langone Medical Center

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: In general, this policy seems to have been conceived without expert input, covers all biological entities in a blanket and overreaching categorization and fails to establish the logic behind the policies.
I believe that this policy revision is unworkable for several overlapping reasons, mostly arising from the apparent classification of all biological entities as one category

The policy as written would seem to require establishing a new and large oversight mechanism to implement or else simply ban useful and innocuous research along with potentially risky research owing to its sweeping generalizations.

1. I do not believe that changing from a list-based approach to a risk-based approach is workable. Who is to assess risk? This will require review of an endless number of experimental proposals and defense on a case by case basis. The other possibility is that the new rules will simply ban all useful research on all biological entities, since there is apparently to be no differentiation between harmless and lethal pathogens.

2. What is “the biological agent”? Similar to point 1., is the proposal to ban all alterations of all biological agents that could alter all replication characteristics that increase their survival?

3. Forbidding "Altering the host range or tropism of the biological agent” is not workable because this is a necessary and standard practice for many biological agents. Without a list-based system that classifies agents according to potential for harm, this bans standard ongoing research.

4. "Generating or reconstituting an eradicated or extinct biological agent.” Is the policy to forbid any thawing of tundra to seek ancient biological entities? This seems unwise. How as this risk been estimated in order to forbid it?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 1. Please provide further clarification on Risk Groups and IBC functions.

3. Continued utility of Risk Groups: 1.Section III-A points to 2 CFR 200.334 for a three year retention period, but then requires minutes and incident reports to stay posted for five years. If an award closes out and the three year clock runs out first, which requirement wins? Institutions need to know whether they are keeping these records solely to satisfy the posting requirement.
2.The policy says a member with a conflict still counts toward quorum. The minutes template says all formal business needs a quorum and that NIH recommends a non-affiliated member be present. Is non-affiliated presence required or just recommended? And if the only non-affiliated members at the meeting have recused themselves, does the committee still have a valid quorum?
3. The incident template requires the PI's name, bars other identifying information, and says the PI's name cannot be redacted. In a two person lab, or when the PI is the person who was exposed, the combination of name, agent, date, position title, and biosafety level identifies the injured employee on a public webpage. How does this work with ADA and HIPAA protections for employee medical information, and with state workers' compensation privacy requirements? We ask that NIH allow the names be withheld.
4. When does the 24 hour clock start? Is it when the exposure is confirmed, or when biosafety first hears about it? We also need to know who at NIH receives the notification and how it gets there. The template says reports must be sent to NIH but gives no address, portal, or file format. Please also clarify whether the clock runs through weekends and federal holidays.
5.The phrase "confirmed or potential laboratory acquired infection" is not defined. Taken literally, almost any needlestick at BSL-2 would meet it. We recommend NIH define this based on the agent and the actual likelihood of infection rather than on whether an exposure happened.
Public posting is tied to NIH's final response. If NIH does not respond, when can the institution post, and when must it? Please set a default timeline so reports do not sit unposted indefinitely while we wait.
6. The scope covers any genetically modified cell, virus, or organism other than plants. Read with Section IV-3, a plasmid in K-12 E. coli would still need delegated review. 7. The exemptions in Section III-F and Appendix C of the current Guidelines appear to be gone. NIH has said one goal is reducing burden for low risk work, and right now there is no exempt tier at all.
8. The definition of laboratory research leaves out deliberate release outside of containment. Field testing is covered under the current Guidelines. Given how much new structure this draft builds around gene drive modified organisms, leaving field release out entirely seems like a gap. Was it intended?
9. The toxin definition is limited to proteins and peptides made by living organisms. That leaves out saxitoxin, tetrodotoxin, T-2 mycotoxin, and other Select Agent toxins that are not proteins. Was this intentional? We suggest matching the Federal Select Agent Program toxin list instead.
10. The prion definition covers disease in humans or animals, but the overall scope is limited to risk to human health. Which one applies to prion and self-aggregating protein work that only affects animals?
11. Biomedical research is defined by NIH mission, yet the policy reaches all research at any institution that receives NIH funding. Would an industry funded agricultural or environmental microbiology project at a university with a single NIH grant be covered? We need this spelled out for affiliated hospitals, separately incorporated research institutes, subrecipients, and shared core facilities.
12. How is the Biosafety Assurance submitted, and how long should we expect review to take? If the effective date arrives and NIH has not yet approved our Assurance, can research continue?
13. The draft allows delegated review of minor amendments but never says what counts as minor. Will NIH publish criteria, or is each IBC expected to define this in its own procedures?

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): As it stands this policy would not apply to Non NIH funded institution's. NIH should build relationships with their neighboring funding oversight bodies if they would like this policy to apply to that group of non NIH funded research . Together you all can build a policy that the other funding bodies can agree to and adapt for research intuitions in which which they provide funding.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1. The draft allows delegated review of minor amendments but never says what counts as minor. Will NIH publish criteria, or is each IBC expected to define this in its own procedures?
2. The sample project overview in the minutes template includes the vector backbone, deletions, transgenes, promoters, routes of administration, and animal models. Posting that level of detail before publication can cost foreign patent rights or breach confidentiality agreements with sponsors. What standard should we apply when redacting unpublished technical detail, and who settles a disagreement about a redaction? The IBC, the institution, or NIH?
3. A BSO is only required for BSL-3, BSL-4, and gene drive work, but the BSO duties have to be assigned to someone regardless. Why not simply require the position and scale the scope to the work being done? Separately, the BSO is a required voting member while also running inspections, investigating incidents, and preparing the risk assessments the committee votes on. Does NIH see an independence problem here? We would ask NIH to consider making the BSO a non-voting member.
4. Each posted item may look harmless on its own. Put the roster, the minutes, the incident reports, and the Assurance disclosures together and you have a map of what agents we hold, who works with them, where, at what containment level, and what has already failed. Please review the posting requirements as a whole for security risk.
5. NIH alone decides containment for novel, emerging, and zoonotic agents, and approves every request to lower containment. There are no published criteria, no deadline, and no appeal. Research stops while we wait. Please explain how these calls will be made and commit to a turnaround time.
6. The draft says research overseen by another federal agency may proceed once that agency approves. Read literally, that could cut the IBC out of anything with a USDA permit, etc. Please confirm IBC review still applies.
7. Please provide further clarification on Risk Groups and IBC functions.
8. Please consider expanding the implementation timeline from Six months to at least one year. New Assurances, new registration reviews, new webpages, new members, and new reporting workflows all hit at once.

6. Other feedback relevant to this resource: 1. Please consider expanding the implementation timeline from Six months to at least one year. New Assurances, new registration reviews, new webpages, new members, and new reporting workflows all hit at once.
2. The exemptions in Section III-F and Appendix C of the current Guidelines appear to be gone. NIH has said one goal is reducing burden for low risk work, and right now there is no exempt tier at all.

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NIH Biosafety Policy Comments

- Section III-A points to 2 CFR 200.334 for a three year retention period, but then requires minutes and incident reports to stay posted for five years. If an award closes out and the three year clock runs out first, which requirement wins? Institutions need to know whether they are keeping these records solely to satisfy the posting requirement.

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- How is the Biosafety Assurance submitted, and how long should we expect review to take? If the effective date arrives and NIH has not yet approved our Assurance, can research continue?

- The draft allows delegated review of minor amendments but never says what counts as minor. Will NIH publish criteria, or is each IBC expected to define this in its own procedures?

- The sample project overview in the minutes template includes the vector backbone, deletions, transgenes, promoters, routes of administration, and animal models. Posting that level of detail before publication can cost foreign patent rights or breach confidentiality agreements with sponsors. What standard should we apply when redacting unpublished technical detail, and who settles a disagreement about a redaction? The IBC, the institution, or NIH?

- A BSO is only required for BSL-3, BSL-4, and gene drive work, but the BSO duties have to be assigned to someone regardless. Why not simply require the position and scale the scope to the work being done? Separately, the BSO is a required voting member while also running inspections, investigating incidents, and preparing the risk assessments the committee votes on. Does NIH see an independence problem here? We would ask NIH to consider making the BSO a non-voting member.

- Each posted item may look harmless on its own. Put the roster, the minutes, the incident reports, and the Assurance disclosures together and you have a map of what agents we hold, who works with them, where, at what containment level, and what has already failed. Please review the posting requirements as a whole for security risk.

- NIH alone decides containment for novel, emerging, and zoonotic agents, and approves every request to lower containment. There are no published criteria, no deadline, and no appeal. Research stops while we wait. Please explain how these calls will be made and commit to a turnaround time.

- The draft says research overseen by another federal agency may proceed once that agency approves. Read literally, that could cut the IBC out of anything with a USDA permit, etc. Please confirm IBC review still applies.

- Please provide further clarification on Risk Groups and IBC functions.

- Please consider expanding the implementation timeline from Six months to at least one year. New Assurances, new registration reviews, new webpages, new members, and new reporting workflows all hit at once.

251. Trustees of Boston College (Boston College)

I am responding: On behalf of an organization

Name: Babak Momeni

Name of Organization: Trustees of Boston College (Boston College)

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious diseases, toxins

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. In the definition of biological agents, the terminology for 'parasites' is not precise. Some organisms may have virulence or pathogenicity that depends on the host state or on the presence of other organisms/microorganisms.
2. In the definition of biological agents: It is unclear whether organisms that do not cause a human disease but aggravate it are included.
3. Definition of ‘Genetic Modification’: The modes of introduction of mutations into cells, organisms, or viruses are defined as ‘passaging, reassortment, chemical or radiological means’. Are other strategies for mutagenesis not covered (for example, ultrasound)?
4. Definition of ‘Novel agent or organism’: The definition as ‘an agent or organism not existing in nature’ is not well-defined. A particular mutation in a bacterial cell that confers antibiotic resistance, for example, is likely to exist in nature.
5. Defining ‘Wild type’ as ‘Naturally occurring organisms, cells, or viruses without deliberately introduced genetic modifications’ is ambiguous. For example, lab domestication of bacterial and fungal species is naturally occurring; is that included in this category? Alternatively, a mutation evolved/engineered in the lab may also be discovered naturally, for example, in antibiotic resistance. Would the lab-engineered strain still be considered wild type?
6. Definition of Toxin: Toxins are defined as ‘a protein or peptide,’ which is incomplete. There are important categories of toxins that cause harm in humans but are not proteins or peptides (e.g., mycotoxins or higher concentrations of some antibiotics).
7. Formatting issue: The abbreviation GDMO is not defined at the beginning of the document (it appears later).

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): 1. “Supervising the performance of laboratory staff to

ensure that the required safety practices and techniques are employed and correcting any errors.” This is not currently part of IBC oversight responsibilities. The mechanisms and extent of this expectation need to be clarified.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: 1. "Adhering to all IBC-approved plans, including emergency response for handling accidental spills, personnel contamination, post-exposure response, loss of containment or release of biohazards, waste disposal, or other incidents involving research covered under the Policy." It is unclear how the IBC-approved emergency response plan (related to biohazards) will be distinguished from the general lab safety emergency response. It is unclear which responsibilities fall under the "IBC-approved" designation, because there is overlap in expectations.
2. Regarding "Submitting the initial research protocol and any subsequent changes that may alter the biorisk assessment of the research to be conducted, to the IBC and NIH (as appropriate), for review and approval." For this requirement, it would be important to clarify what level of alteration of the biorisk should be reported and what the expected timeline is for the IBC or NIH's review and approval.

Description: Comments from the Boston College community

252. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: IBC administrator

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As a biosafety compliance professional responsible for assisting investigators, institutional review bodies, and institutional officials with implementing biosafety requirements, I am concerned that several key definitions within the draft policy lack the specificity needed to support consistent implementation across institutions. Throughout the document, broad concepts are introduced without sufficient objective criteria, examples, or decision frameworks. As a result, institutions acting in good faith may reach substantially different conclusions regarding whether research falls within scope and what oversight obligations apply.

I am particularly concerned that the policy claims to be a policy about human biosafety concerns but retains many environmental considerations. The policy essentially takes the NIH guidelines for r/sNA and picks and chooses key concepts from that policy to keep and others to discard without a justification provided.

Biological Agent Definition

The proposed definition of Biological Agent appears substantially broader than existing frameworks and may encompass a wide range of research activities that have historically not been subject to significant biosafety oversight.

From an implementation perspective, institutions will need to determine whether ongoing and proposed research activities fall within the scope of the policy. However, the definition does not clearly establish whether the policy is intended primarily to address risks to human health or whether it is intended to encompass broader concerns such as ecological impacts, environmental risks, agricultural considerations, animal health concerns, self-aggregating proteins, prions, toxins, and other biological materials.

Institutions will need concrete examples demonstrating what NIH intends to include and exclude. Without such examples, different institutions may apply substantially different interpretations to similar activities.

Emerging Organism Definition

The definition of Emerging Organism presents significant implementation challenges because it provides no clear mechanism for determining when an organism becomes "emerging."

As written, the policy does not indicate:
• Whether emergence should be evaluated at a local, regional, national, or global level.
• What information sources institutions should rely upon.
• Who is responsible for making the determination.
• Whether determinations should be periodically reassessed.

As someone who routinely assists investigators in determining applicable oversight requirements, I would find it difficult to provide consistent guidance under the current definition.

NIH should provide objective criteria, examples, and authoritative reference sources to support institutional decision making.

Novel Organism Definition

Similar concerns exist regarding the definition of Novel Organism.

The term "novel" may reasonably be interpreted in numerous ways, including:
• Novel taxonomy.
• Novel genetic composition.
• Novel phenotype.
• Novel pathogenicity.
• Novel environmental characteristics.
• Novel host range.

The policy does not clearly identify what form of novelty is intended to trigger additional oversight requirements.
Without greater specificity, institutions may apply significantly different standards to similar research activities.

Zoonotic Agents
The policy introduces concepts such as organisms that are "reasonably suspected" to infect humans. While this language may provide flexibility, it also introduces substantial subjectivity.
Institutions would benefit from guidance regarding:
• Acceptable evidence standards.
• Authoritative data sources.

• Documentation expectations.
• Reassessment requirements as scientific knowledge evolves.
Without these elements, institutions may develop inconsistent approaches to evaluating zoonotic agents.

Scope of Oversight for Genetically Modified Organisms and Cells
One of my primary implementation concerns involves the potential scope of oversight for genetically modified organisms and cells.
The draft does not clearly address how common research materials previously exempted or where the draft policy creates ambiguity as to whether they are included or excluded including:
• Recombinant yeast systems.
• Recombinant bacterial systems.
• Commercially available modified cell lines.
• Gene-edited cell lines.
• Immortalized cell lines.
• Transgenic animals.
• Genome-edited animal models.

Because these systems are widely used throughout the research enterprise, even small differences in interpretation could have significant consequences for institutional workload, review timelines, and investigator burden.
NIH should provide detailed examples illustrating intended oversight pathways for common research models.

Exclusion of Plants
The apparent exclusion of genetically modified plants is difficult to reconcile with the broader themes of the policy.
The draft repeatedly emphasizes phenotype-based risk assessment, potential environmental impacts, and emerging biotechnologies. However, genetically modified plants appear to receive substantially different treatment.
Additional explanation regarding the scientific and regulatory rationale for this distinction would improve consistency and transparency.
Recommendation
NIH should provide clearer definitions, detailed examples, decision aids, and implementation guidance that allows institutions to consistently determine what research falls within scope.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support the policy's emphasis on risk assessment and the concept of matching oversight to risk. However, the current draft frequently directs institutions to perform risk assessments without providing sufficient guidance regarding how those assessments should be conducted.
As written, the policy may inadvertently create wide variation in oversight practices among institutions.
Risk Assessment Methodology
The policy treats risk assessment as the foundation for numerous oversight decisions, including:
• Containment determinations.
• Oversight pathways.

• Reporting obligations.
• Institutional review requirements.

However, the policy provides little practical guidance on how institutions should conduct these assessments.

The draft does not adequately address:

• Weighting of risk factors.
• Management of uncertainty.
• Documentation expectations.
• Reviewer qualifications.
• Required elements of risk assessments.

If risk assessment is intended to become the central decision-making mechanism under the policy, NIH should provide standardized methodologies, decision trees, and worked examples.

Delegated Review

The delegated review provisions create significant operational uncertainty.

The draft does not clearly explain:

• Which activities qualify.
• Who performs the review.
• Required documentation.
• Reporting obligations to the IBC.
• Record retention expectations.

Because many historically exempt activities may now move into delegated review pathways, even small ambiguities could result in significant documentation burden.

As someone involved in protocol review workflows and committee support activities, I anticipate institutions struggling to implement these provisions consistently without additional guidance.

Well-Characterized Systems

Multiple sections of the policy rely upon concepts such as "well-characterized organisms" and "well-characterized cell lines."

The policy does not establish objective criteria for determining when a biological system is sufficiently characterized.

Questions likely to arise include:

• Does widespread use constitute characterization?
• Is published literature sufficient?
• Are commercial products automatically considered characterized?
• How should modified derivatives be evaluated?

These classifications may directly affect oversight requirements and therefore require greater clarity.

Roles and Responsibilities

Throughout the policy, responsibilities are frequently assigned to:

• Institutions.
• Institutional Officials.
• Biosafety Officers.
• Institutional Biosafety Committees.
• Principal Investigators.
• NIH.

However, the distinctions among these responsibilities are not always clear.

An implementation matrix identifying primary, supporting, and oversight responsibilities would promote consistency and reduce institutional confusion.
Recommendation
NIH should provide implementation resources that explain not only what decisions must be made but how those decisions are expected to be made in practice.

3. Continued utility of Risk Groups: The draft appears to retain Risk Groups while simultaneously emphasizing broader risk assessment principles. However, the relationship among Risk Groups, Biosafety Levels, and institutional risk assessment is not fully explained.
As someone responsible for assisting investigators and reviewers in applying these concepts, I am concerned that institutions may struggle to determine how these frameworks interact.
Utility of Risk Groups
The policy introduces numerous considerations that extend beyond traditional Risk Group frameworks, including:
• Host range.
• Environmental persistence.
• Ecological effects.
• Gene-drive characteristics.
• Novel phenotypes.
• Synthetic biology considerations.
While these factors may be important, it is unclear whether Risk Groups remain the primary classification tool or have become only one component of a broader assessment process.
Expanded Definition of Genetic Modification
The inclusion of passaging, reassortment, chemical mutagenesis, and radiological mutagenesis raises important implementation questions.
The policy does not clearly explain:
• Why these methods warrant oversight.
• Whether oversight is based on methodology or phenotype.
• How naturally occurring changes should be treated.
• How institutions should document these determinations.
These questions will directly affect oversight decisions and should be addressed more explicitly.
Recommendation
NIH should provide detailed case studies demonstrating how Risk Groups, containment levels, and institutional risk assessment are expected to interact under the new framework.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The success of voluntary adoption will depend heavily on whether institutions can understand and implement the framework in a practical and resource-conscious manner.
Many significant implementation details remain undefined.
Supporting Resources
Throughout the policy, NIH references future:
• Guidance documents.
• Templates.
• Best practices.

• Reporting tools.
• Educational materials.

However, institutions are currently being asked to evaluate the framework without reviewing these resources.

As an individual who would likely participate in developing institutional implementation strategies, I find it difficult to estimate the true impact of the policy without these supporting materials.

National Biosafety Data and Safety Analysis Center

The proposed NBDSAC may serve an important role, but its operational model remains unclear.

Institutions would benefit from additional information regarding:

• Governance.
• Data management.
• Reporting expectations.
• Data utilization.
• Confidentiality protections.

Recommendation

NIH should consider releasing implementation resources alongside future policy drafts to support more informed public feedback.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The transparency and reporting provisions represent one of the most significant operational changes within the draft policy. While transparency is important, several provisions may create substantial burden without a clearly articulated biosafety benefit.

Reportable Incidents

The policy would benefit from clearer distinctions between:

• Biosafety incidents.
• Near misses.
• Occupational injuries.
• Facility events.
• Equipment failures.
• Administrative errors.

Institutions require objective reporting thresholds to promote consistency.

Without clear thresholds, similar events may be reported differently across institutions.

Twenty-Four-Hour Reporting Requirements

The proposed twenty-four-hour reporting requirement raises practical implementation concerns.

Immediately following an incident, institutional efforts are focused on:

• Protecting personnel.
• Stabilizing operations.
• Conducting preliminary assessments.
• Determining root causes.

At that stage, critical facts are often still developing.

NIH should clarify what information is realistically expected within the first twenty-four hours and how preliminary reporting differs from final investigative reporting.

Additionally, NIH should consider the practical value and intended purpose of the initial notification requirement. If the primary purpose of the notification is simply to establish awareness of an event and a timeline for submission of a subsequent investigative report, it is unclear what advantage a 24-hour

reporting requirement provides compared to a longer reporting timeframe, such as 72 hours.
During the initial stages of incident response, institutional efforts are appropriately focused on personnel safety, medical evaluation where necessary, containment, fact gathering, and assessment of reportability. These activities often occur while information is still developing and before the institution has sufficient details to provide meaningful context regarding the event.
Based on my professional experience submitting incident reports to NIH, initial notifications are rarely accompanied by immediate feedback, consultation, or response from NIH that would alter the institution's immediate response activities. If NIH does not anticipate playing an active role during the initial response phase, the policy should clearly articulate the benefit of a 24-hour reporting requirement and how that benefit outweighs the administrative burden imposed on institutions during a critical response period. Absent such justification, a modestly longer reporting window may allow institutions to provide more accurate and useful information while maintaining timely federal awareness of significant incidents.
A slightly longer reporting window may also improve the quality and reliability of the information submitted. Institutions would be better positioned to provide a more accurate description of the event, preliminary causal factors, immediate corrective actions, and an informed assessment of actual risk rather than submitting notifications based on incomplete information that may subsequently require correction.
Public Disclosure Requirements
Public posting requirements warrant careful consideration.
While transparency can promote accountability, disclosure provisions should also consider:
• Personnel privacy.
• Institutional confidentiality.
• Biosecurity considerations.
• Potential disincentives to self-reporting.
In some research communities, even heavily redacted reports may allow affected laboratories or individuals to be identified.
This risk should be carefully evaluated.
Meeting Minutes
The policy should clearly define:
• What constitutes approved minutes.
• Publication timelines.
• Redaction standards.
• Treatment of sensitive information.
Institutions will struggle to implement consistent practices without this guidance.
Recommendation
NIH should adopt a more risk-based approach to reporting and provide model templates reflecting privacy, biosafety, and biosecurity considerations. NIH should avoid prescribing a specific institutional governance process for the approval and publication of IBC meeting minutes. Institutions already operate under established procedures for record review, approval, and public posting. The policy's objective should be timely public availability of approved minutes rather than dictating how institutions reach approval. Allowing institutions to define approved minutes through their own documented procedures and requiring publication within a reasonable timeframe, such as 72 hours after final approval, would better accommodate institutional variations while still supporting transparency.

6. Other feedback relevant to this resource: My single greatest concern with the draft policy is that many of its most consequential provisions rely upon implementation resources that have not yet been released.

As someone who would likely be involved in translating this policy into institutional procedures, workflows, committee practices, investigator guidance, and training materials, I find it difficult to assess the practicality of many requirements in the absence of those resources.

Operational Planning Challenges

Institutions cannot accurately estimate:

• Staffing requirements.
• Training needs.
• Information technology modifications.
• Committee workload.
• Administrative burden.
• Compliance costs.

Without these estimates, it is difficult to assess the full impact of the policy.

NIH Review Processes

Several provisions rely upon future NIH review and consultation mechanisms involving novel, emerging, and other specialized biological agents.

However, the draft provides limited information regarding:

• Responsible offices.
• Review timelines.
• Submission processes.
• Escalation procedures.
• Appeals mechanisms.

Because institutional decisions may depend upon these processes, additional detail is necessary.

Institutional Resources

Successful implementation will require significant investments in:

• Policy development.
• Training programs.
• Investigator education.
• Electronic management systems.
• Committee administration.
• Risk assessment programs.

Many institutions will need substantial lead time to complete this work.

Implementation Timeline

The proposed six-month implementation timeline appears unlikely to provide sufficient time for institutions to:

• Revise policies.
• Develop procedures.
• Build training programs.
• Modify software systems.
• Train stakeholders.
• Establish governance structures.

A phased implementation approach would appear more realistic and likely more successful.

Recommendation

NIH should provide implementation guidance before finalizing requirements, expand stakeholder engagement around operational impacts, and consider a phased implementation strategy that allows institutions sufficient time to develop sustainable compliance programs.

From an implementation and governance perspective, I am concerned that the draft policy relies heavily on future guidance documents to define many of the substantive standards institutions will ultimately be expected to meet. While guidance can be an effective tool for providing examples, best practices, and implementation support, it should not serve as the primary mechanism for establishing core compliance requirements.

As currently written, many key standards, processes, and expectations remain undefined and are deferred to future guidance documents that have not yet been released. This creates challenges for stakeholders attempting to evaluate the practical impact of the policy and limits the ability of institutions to provide meaningful feedback during the public comment process.

More broadly, substantive compliance obligations should be established within the policy itself, where they are subject to public review, comment, and transparency. Guidance documents should then be used to explain, interpret, and operationalize those requirements rather than create them.

I recommend that NIH incorporate the core standards, decision criteria, and institutional expectations directly within the policy and reserve guidance documents for implementation examples, recommended practices, case studies, and other supporting resources. Doing so would improve transparency, provide greater regulatory certainty, and allow stakeholders to more fully evaluate the impact of the proposed framework before it is finalized.

253. Cornell University

I am responding: On behalf of an organization

Name:

Name of Organization: Cornell University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft policy substantially expands biosafety oversight beyond the framework historically established under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. While we recognize the rationale for updating oversight frameworks to reflect emerging technologies and new categories of biological research, the boundaries of covered research are not always clearly defined. For example, the draft appears to bring genetically modified cells, organisms, and viruses broadly into scope while introducing previously unaddressed genetic modification techniques, including passaging, reassortment, chemical mutagenesis and radiological mutagenesis, creating uncertainty regarding the intended scope of institutional oversight and review requirements.

Throughout the policy, there appears to be tension between provisions focused on risks to human health and provisions that address broader ecological, environmental, agricultural, and biotechnology considerations. As a result, it is not always clear whether the policy is intended primarily as a human-health biosafety framework or a broader biotechnology oversight framework. The policy should clearly define whether it is intended to address only direct human health risks or broader biological risks affecting animal health, agriculture, food systems, and the environment, and ensure that any inclusion or exclusion of these hazards is scientifically justified and applied consistently. Additionally, the policy would benefit from clearly stating whether activities previously exempted under the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules are now subject to institutional review requirements.

Additional clarification regarding the intended scope of covered research would improve implementation consistency and assist institutions in determining when activities are subject to policy requirements.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The draft policy places institutional risk assessment at the center of numerous oversight decisions, including containment determinations, review pathways, incident reporting obligations, and evaluation of genetically modified, emerging, zoonotic, and novel biological systems. While institutional flexibility is important, the policy provides limited guidance regarding how risk assessments should be conducted, how competing factors

should be evaluated, and how uncertainty should be managed. As written, institutions with similar expertise may reasonably arrive at different conclusions when evaluating comparable research activities.

The draft policy also does not clearly describe the status of institutional risk assessments once they have been completed. Institutions may encounter complex research activities for which a risk assessment indicates the work is consistent with the policy, but for which limited NIH precedent or guidance exists. In these situations, institutions will rely upon the expertise of their Institutional Biosafety Committee (IBC)s, Biosafety Officer (BSO)s, and subject matter experts to conduct risk assessments and implement appropriate containment measures. The policy would benefit from clarifying the extent to which institutions may rely upon well-documented, good-faith risk assessments conducted in accordance with the policy until NIH provides alternative guidance or determinations. If consistency across the research enterprise is an intended objective, NIH should consider providing additional methodologies, examples, implementation guidance, and decision frameworks to support institutional decision-making.

3. Continued utility of Risk Groups: The draft policy frequently relies upon subjective phrases such as "appropriate," "reasonable," "well-characterized," "periodic," "immediate," and "maximum extent possible." Although such concepts are commonly used in performance-based regulatory frameworks, the policy often does not identify the responsible decision-maker or provide criteria supporting consistent interpretation.

Additional clarification regarding decision criteria, responsible parties, and institutional decision-making authority would improve implementation consistency. Where subjective standards are necessary, the policy should clearly identify the institutional office, official, or committee responsible for making the determination and provide sufficient criteria to support consistent application. The policy should allow institutions to make and document these determinations through their established biosafety oversight programs rather than relying on repeated NIH interpretation of individual situations.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The draft policy introduces substantial new administrative requirements, including Biosafety Assurances, public-facing website requirements, incident reporting obligations, expanded documentation requirements, public posting of records, and delegated-review reporting obligations.

While we understand the goals associated with these requirements, the policy would benefit from a clearer explanation of how these activities are expected to improve biosafety outcomes, strengthen biosafety culture, reduce incidents, or otherwise advance the objectives of the policy. Institutions will ultimately need to dedicate finite resources toward policy implementation. Additional discussion regarding the intended benefits of major administrative requirements would assist institutions in understanding the rationale for these changes and evaluating implementation priorities.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Transparency is a central feature of the draft policy and represents a significant shift in biosafety oversight. While transparency is an important objective, the policy would benefit from a clearer explanation regarding how public disclosure is expected to improve biosafety outcomes, strengthen safety culture, reduce incidents, or improve accountability.

The transparency provisions may also unintentionally discourage reporting by increasing concerns regarding confidentiality, public scrutiny, and potential re-identification of individuals involved in incidents. Without clear definitions of reportable incidents and reporting timelines, institutions may be compelled to report routine operational events, particularly in BSL-3 and BSL-4 environments, that do not compromise containment or present a credible biosafety consequence, increasing administrative burden and potentially undermining a strong reporting culture. A strong biosafety culture depends upon prompt and candid reporting of mistakes, near-misses, and incidents. Institutions may be less likely to achieve that outcome if investigators and staff perceive that incident information will become publicly accessible.

Additionally, the policy should more carefully consider the biosecurity implications of its transparency requirements. While individual disclosures may appear low risk in isolation, the cumulative publication of meeting minutes, incident reports, research descriptions, investigator information, biological agents, and facility details may create an aggregate risk by allowing external parties to assemble a more complete picture of an institution's biological research activities, capabilities, and holdings.
We encourage NIH to further evaluate how transparency objectives can be balanced with biosafety, biosecurity, privacy, and reporting-culture considerations.

6. Other feedback relevant to this resource: Many critical operational details appear to be deferred to future implementation resources, guidance documents, templates, and supporting materials that are not currently available for review. As a result, institutions are being asked to evaluate and comment on a framework whose practical implementation remains partially undefined.
Without access to these materials, institutions cannot accurately assess implementation costs, staffing requirements, information technology needs, training expectations, compliance timelines, or administrative burden.

We encourage NIH to release draft implementation resources, guidance materials, templates, and decision frameworks for public review. Because these materials will likely have a substantial impact on how institutions comply with the policy, we believe stakeholders would benefit from an additional opportunity to review and comment on these resources before the policy is finalized.

The draft policy substantially expands responsibilities for institutions, IBCs, BSOs, PIs, and NIH. However, the policy frequently assigns responsibilities without clearly identifying authority, accountability, or implementation pathways. Similarly, the policy assigns significant new responsibilities to NIH without clearly identifying which offices will be responsible for implementation, policy interpretation, review activities, and institutional support. Successful implementation will require both institutions and NIH to understand who is responsible for specific activities and how those responsibilities will be operationalized in practice. Additional clarity regarding governance structures, roles, responsibilities, and decision-making authority would significantly improve implementation and compliance.

The proposed six-month implementation period appears insufficient given the scale of changes contemplated by the policy. Institutions will likely need to revise policies, modify review systems, update training programs, establish new reporting workflows, develop public-facing transparency infrastructure, update committee procedures, review existing research portfolios to identify newly covered activities, and develop and implement new procedures for activities newly covered under the policy, all of which

will require sufficient implementation time. Implementation may be particularly challenging if activities that were previously exempt under the NIH Guidelines become subject to institutional review requirements under the new framework. At the same time, NIH will need to develop implementation guidance, establish review processes, review Biosafety Assurances, respond to institutional questions, and operationalize several new oversight functions. Given the breadth of these changes and the continued reliance on future guidance documents, NIH should consider extending the implementation period, adopting a phased implementation strategy, or providing additional transition time following release of final implementation resources. A longer implementation timeline would improve consistency, reduce institutional burden, and allow both NIH and the research community sufficient time to establish sustainable compliance programs.

Cornell University and Weill Cornell Medicine appreciate NIH's efforts to modernize biosafety oversight and supports the shared goal of promoting the safe, responsible, and effective conduct of biological research. With significant implementation details still pending, institutions are unable to fully assess the policy's impact. We recommend that NIH release supporting guidance for public review and establish an extended implementation timeline that reflects the breadth of changes required. We encourage NIH to continue engaging with stakeholders as the policy evolves and to consider additional clarification, implementation guidance, and phased implementation strategies that support consistent adoption across the research community. We look forward to continued collaboration in advancing a biosafety framework that is both effective and practical for institutions to implement.

Uploaded File: Cornell-Public-Comment-to-Proposed-NIH-Biosafety-Policy_10-16-26.pdf

Cornell University

October 16, 2026

NIH Office of Science Policy
6705 Rockledge Drive, Suite 630, MSC-7985
Bethesda, MD 20892-7985

Re: Draft NIH Biosafety Policy for Research Involving Biohazards

To Whom It May Concern:

Cornell University and Weill Cornell Medicine appreciate the opportunity to provide comments on the Draft NIH Biosafety Policy for Research Involving Biohazards. We support NIH's efforts to modernize biosafety oversight and recognize the importance of maintaining robust institutional biosafety programs capable of addressing advances in biotechnology, synthetic biology, emerging biological systems, and evolving research methodologies.

We commend the effort to develop a framework that advances biosafety oversight while supporting a diverse research enterprise. However, several aspects of the proposal would benefit from additional clarification, implementation guidance, and additional stakeholder engagement prior to finalization. The comments below are intended to support this effort by identifying areas where additional clarity, guidance, and alignment will help institutions apply the policy consistently and effectively.

1. Expansion and Definition of Covered Research

The draft policy substantially expands biosafety oversight beyond the framework historically established under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. While we recognize the rationale for updating oversight frameworks to reflect emerging technologies and new categories of biological research, the boundaries of covered research are not always clearly defined. For example, the draft appears to bring genetically modified cells, organisms, and viruses broadly into scope while introducing previously unaddressed genetic modification techniques, including passaging, reassortment, chemical mutagenesis and radiological mutagenesis, creating uncertainty regarding the intended scope of institutional oversight and review requirements.

Throughout the policy, there appears to be tension between provisions focused on risks to human health and provisions that address broader ecological, environmental, agricultural, and biotechnology considerations. As a result, it is not always clear whether the policy is intended primarily as a human-health biosafety framework or a broader biotechnology oversight framework. The policy should clearly define whether it is intended to address only direct human health risks or broader biological risks affecting animal health, agriculture, food systems, and the environment, and ensure that any inclusion or exclusion of these hazards is scientifically justified and applied consistently. Additionally, the policy would benefit from clearly stating whether activities previously exempted

under the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules are now subject to institutional review requirements.

Additional clarification regarding the intended scope of covered research would improve implementation consistency and assist institutions in determining when activities are subject to policy requirements.

2. Reliance on Risk Assessment as the Principal Oversight Mechanism

The draft policy places institutional risk assessment at the center of numerous oversight decisions, including containment determinations, review pathways, incident reporting obligations, and evaluation of genetically modified, emerging, zoonotic, and novel biological systems.

While institutional flexibility is important, the policy provides limited guidance regarding how risk assessments should be conducted, how competing factors should be evaluated, and how uncertainty should be managed. As written, institutions with similar expertise may reasonably arrive at different conclusions when evaluating comparable research activities.

The draft policy also does not clearly describe the status of institutional risk assessments once they have been completed. Institutions may encounter complex research activities for which a risk assessment indicates the work is consistent with the policy, but for which limited NIH precedent or guidance exists. In these situations, institutions will rely upon the expertise of their Institutional Biosafety Committee (IBC)s, Biosafety Officer (BSO)s, and subject matter experts to conduct risk assessments and implement appropriate containment measures. The policy would benefit from clarifying the extent to which institutions may rely upon well-documented, good-faith risk assessments conducted in accordance with the policy until NIH provides alternative guidance or determinations.

If consistency across the research enterprise is an intended objective, NIH should consider providing additional methodologies, examples, implementation guidance, and decision frameworks to support institutional decision-making.

3. Reliance on Subjective Standards

The draft policy frequently relies upon subjective phrases such as "appropriate," "reasonable," "well-characterized," "periodic," "immediate," and "maximum extent possible."

Although such concepts are commonly used in performance-based regulatory frameworks, the policy often does not identify the responsible decision-maker or provide criteria supporting consistent interpretation.

Additional clarification regarding decision criteria, responsible parties, and institutional decision-making authority would improve implementation consistency. Where subjective standards are necessary, the policy should clearly identify the institutional office, official, or committee responsible for making the determination and provide sufficient criteria to support consistent application. The policy should allow institutions to make and document these determinations through their established biosafety oversight programs rather than relying on repeated NIH interpretation of individual situations.

4. Administrative Burden Relative to Biosafety Benefit

The draft policy introduces substantial new administrative requirements, including Biosafety Assurances, public-facing website requirements, incident reporting obligations, expanded documentation requirements, public posting of records, and delegated-review reporting obligations.

While we understand the goals associated with these requirements, the policy would benefit from a clearer explanation of how these activities are expected to improve biosafety outcomes, strengthen biosafety culture, reduce incidents, or otherwise advance the objectives of the policy.

Institutions will ultimately need to dedicate finite resources toward policy implementation. Additional discussion regarding the intended benefits of major administrative requirements would assist institutions in understanding the rationale for these changes and evaluating implementation priorities.

5. Transparency Requirements, Reporting Culture, and Biosecurity Considerations

Transparency is a central feature of the draft policy and represents a significant shift in biosafety oversight.

While transparency is an important objective, the policy would benefit from a clearer explanation regarding how public disclosure is expected to improve biosafety outcomes, strengthen safety culture, reduce incidents, or improve accountability.

The transparency provisions may also unintentionally discourage reporting by increasing concerns regarding confidentiality, public scrutiny, and potential re-identification of individuals involved in incidents. Without clear definitions of reportable incidents and reporting timelines, institutions may be compelled to report routine operational events, particularly in BSL-3 and BSL-4 environments, that do not compromise containment or present a credible biosafety consequence, increasing administrative burden and potentially undermining a strong reporting culture. A strong biosafety culture depends upon prompt and candid reporting of mistakes, near-misses, and incidents. Institutions may be less likely to achieve that outcome if investigators and staff perceive that incident information will become publicly accessible.

Additionally, the policy should more carefully consider the biosecurity implications of its transparency requirements. While individual disclosures may appear low risk in isolation, the cumulative publication of meeting minutes, incident reports, research descriptions, investigator information, biological agents, and facility details may create an aggregate risk by allowing external parties to assemble a more complete picture of an institution's biological research activities, capabilities, and holdings.

We encourage NIH to further evaluate how transparency objectives can be balanced with biosafety, biosecurity, privacy, and reporting-culture considerations.

6. Reliance on Future Guidance Documents

Many critical operational details appear to be deferred to future implementation resources, guidance documents, templates, and supporting materials that are not currently available for review.

As a result, institutions are being asked to evaluate and comment on a framework whose practical implementation remains partially undefined.

Without access to these materials, institutions cannot accurately assess implementation costs, staffing requirements, information technology needs, training expectations, compliance timelines, or administrative burden.

We encourage NIH to release draft implementation resources, guidance materials, templates, and decision frameworks for public review. Because these materials will likely have a substantial impact on how institutions comply with the policy, we believe stakeholders would benefit from an additional opportunity to review and comment on these resources before the policy is finalized.

7. Governance, Authority, and Implementation Structure

The draft policy substantially expands responsibilities for institutions, IBCs, BSOs, PIs, and NIH. However, the policy frequently assigns responsibilities without clearly identifying authority, accountability, or implementation pathways.

Similarly, the policy assigns significant new responsibilities to NIH without clearly identifying which offices will be responsible for implementation, policy interpretation, review activities, and institutional support.

Successful implementation will require both institutions and NIH to understand who is responsible for specific activities and how those responsibilities will be operationalized in practice. Additional clarity regarding governance structures, roles, responsibilities, and decision-making authority would significantly improve implementation and compliance.

8. Implementation Timeline

The proposed six-month implementation period appears insufficient given the scale of changes contemplated by the policy.

Institutions will likely need to revise policies, modify review systems, update training programs, establish new reporting workflows, develop public-facing transparency infrastructure, update committee procedures, review existing research portfolios to identify newly covered activities, and develop and implement new procedures for activities newly covered under the policy, all of which will require sufficient implementation time. Implementation may be particularly challenging if activities that were previously exempt under the NIH Guidelines become subject to institutional review requirements under the new framework. At the same time, NIH will need to develop implementation guidance, establish review processes, review Biosafety Assurances, respond to institutional questions, and operationalize several new oversight functions.

Given the breadth of these changes and the continued reliance on future guidance documents, NIH should consider extending the implementation period, adopting a phased implementation strategy, or providing additional transition time following release of final implementation resources.

A longer implementation timeline would improve consistency, reduce institutional burden, and allow both NIH and the research community sufficient time to establish sustainable compliance programs.

Conclusion

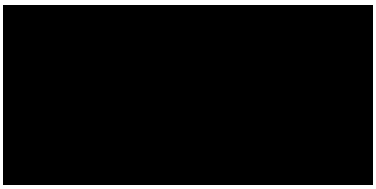
Cornell University and Weill Cornell Medicine appreciate NIH's efforts to modernize biosafety oversight and supports the shared goal of promoting the safe, responsible, and effective conduct of biological research. With significant implementation details still pending, institutions are unable to fully assess the policy's impact. We recommend that NIH release supporting guidance for public review and establish an extended implementation timeline that reflects the breadth of changes required. We encourage NIH to continue engaging with stakeholders as the policy evolves and to consider additional clarification, implementation guidance, and phased implementation strategies that support consistent adoption across the research community. We look forward to continued collaboration in advancing a biosafety framework that is both effective and practical for institutions to implement.

Thank you for the opportunity to provide feedback on this important policy initiative.

Respectfully submitted,



Hugh C. Hemmings, Jr, MD, PhD, FRCA
Senior Associate Dean for Research
Weill Cornell Medicine



Gary Koretzky, MD, PhD
Vice Provost for Research
Cornell University

254. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biosafety

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Many definitions need added and/or clarified.

Reporting incidents with names and grant numbers could kill reporting culture and cause PIs to not report. If the intention is to provide robust metrics related to incidents, it can be done by scrubbing of personal identifying information and used to track and trend that way.

Public posting could share agent information with bad actors who could try to come on campus and steal.

NIH would need to provide training and financial support to prop up. Indirect spending cuts have already slashed budgets for research compliance.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

255. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Administrator of Biosafety

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH_Comment_supporting-CSHEMA-submitted-comments.pdf

Subject: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Support for CSHEMA Recommendations

To Whom It May Concern:

I am submitting this comment in response to the National Institutes of Health (NIH) effort to modernize and strengthen the oversight of biosafety.

I support the comment submitted by the **Campus Safety, Health, and Environmental Management Association (CSHEMA)** regarding this effort. CSHEMA's comment appropriately reflects the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

As an individual Biosafety Officer, my work would be directly impacted by a new NIH policy on biosafety and I support the recommendations outlined by CSHEMA.

Thank you for the opportunity to comment.

Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards

Response to NOT-OD-26-112

October 12, 2026

Submitted Electronically

The Campus Safety, Health, and Environmental Management Association (CSHEMA) is the premier association for environmental health and safety leadership in higher education. CSHEMA represents institutions that range from large research-intensive universities with mature biosafety programs to smaller colleges that may have limited or no dedicated biosafety staff. Our members include biosafety professionals, environmental health and safety practitioners, and institutional leaders responsible for implementing biosafety requirements across diverse research and teaching environments.

CSHEMA appreciates NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions. **Due to such uncertainty in the final requirements, CSHEMA encourages NIH to provide an opportunity for public review and comment on the next draft before it is finalized.**

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." The policy should clarify whether precautionary post exposure prophylactic treatment is considered "agent-specific treatment". It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

6. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

CSHEMA recommends that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

Conclusion

CSHEMA supports NIH's goal of modernizing biosafety oversight and appreciates the draft's movement toward broader risk awareness, clearer incident thresholds, delegated review, and national safety learning. For the policy to succeed, however, modernization must strengthen the institutional systems that perform biosafety work rather than simply expand their obligations.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified

local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

CSHEMA respectfully requests that NIH revise the draft consistent with these recommendations, release complete implementation materials for public review, pilot key templates and processes, and provide a minimum 24-month phased implementation period. CSHEMA welcomes continued engagement and would be pleased to assist NIH in testing implementation resources or gathering additional institutional perspectives.

Sincerely,



Robin Izzo
President
Campus Safety, Health, and Environmental Management Association

256. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

257. Battelle Memorial Institute, Pacific Northwest Division

I am responding: On behalf of an organization

Name: John M. Robinson

Name of Organization: Battelle Memorial Institute, Pacific Northwest Division

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached file for comments

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached file for comments

3. Continued utility of Risk Groups: See attached file for comments

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attached file for comments

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached file for comments

6. Other feedback relevant to this resource: See attached file for comments

Uploaded File: Comments-on-Draft-NIH-Biosafety-Policy-final-2026.10.15.pdf

Battelle Memorial Institute, Pacific Northwest Division Response to Request for Information: Draft NIH Biosafety Policy for Research Involving Biohazards

Introduction

Battelle Memorial Institute, Pacific Northwest Division (Battelle PNWD) has operated the Department of Energy's (DOE) Pacific Northwest National Laboratory (PNNL) since 1965. PNNL's scientific discovery mission includes research that lays a foundation for innovations in 22 core capabilities, accelerating scientific discovery and positioning the U.S. for global leadership in the bioeconomy. Discovering how biological systems operate can advance energy research and the bioeconomy, generating new ways to optimize bioenergy source materials, advance biomanufacturing, and grow stronger crops. Harnessing the power of these systems can also safeguard the environment, bolster national security, and improve human health.

Conducting cutting-edge research safely has been of paramount importance to Battelle PNWD throughout its 60 years of operating experience at PNNL. As such, Battelle PNWD has rich experience in the implementation of biological safety measures. This long history and deep expertise have informed the responses, comments, and recommendations below.

Responses to Request for Information (RFI)

1. *Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed*.
    a. It is unclear what materials and research scopes require formal registration and approval versus general institutional oversight. The boundaries of what is captured under this draft policy remain fluid and unworkable. NIH should create a comprehensive, unambiguous table detailing exactly which biological materials require registration, which require full Institutional Biosafety Committee (IBC) approval, and which are exempt.
    b. The draft's definition of "toxin" is scientifically narrow, failing to clearly capture or account for high-consequence non-proteinaceous toxins (e.g., small molecule endotoxins, mycotoxins, algal toxins). NIH should expand the definition of toxins to explicitly encompass both proteinaceous and non-proteinaceous biological toxins.
    c. The current scope does not define what constitutes a "laboratory setting." It remains ambiguous whether "field work" – which lacks the physical containment controls of a traditional four-walled laboratory – has been

evaluated or included under this policy. NIH should explicitly define "laboratory setting" and clarify the policy's jurisdiction regarding field research, ecological sampling, and vector-borne pathogen fieldwork.

d. The draft lacks clarity regarding the precise threshold at which material is deemed "biological." Crucially, it fails to define the degradation endpoint – the point at which a biological agent is sufficiently broken down or inactivated to no longer be classified as biological material under this policy. NIH should insert clear, quantitative definitions establishing the baseline for what constitutes biological material, alongside validated criteria for complete inactivation/degradation where policy oversight ceases.
e. Section V mandates that risk mitigation protocols must be implemented to "lower the risks to an 'acceptable level.'" An "acceptable level" is a subjective, non-scientific phrase that cannot be uniformly enforced or audited. NIH should replace "acceptable level" with concrete, objective biosafety benchmarks (e.g., "mitigated to containment levels that prevent accidental exposure or release as validated by institutional risk assessment").
f. The draft's handling of "genetic modification" lacks specificity regarding origin, function, or source material that made the historic recombinant DNA (rDNA) guidelines highly effective. This dilution of terms creates compliance ambiguity. NIH should restore the explicit, technically precise definitions of genetic modification found in the 2024 NIH Guidelines, providing clarity regarding synthetic nucleic acids, source organisms, and functional impacts.
g. The draft policy limits the guidelines' focus to human health, omitting comprehensive protections for animal health and environmental reservoirs (e.g., agricultural plants and soils). The explicit exclusion of Genetically Modified Organisms (GMO) plants via the phrase "other than plants" creates a regulatory gap. NIH should expand the scope of its guidelines to include environmental and animal health impact assessments. NIH should replace the exclusionary phrase "other than plants" with a precise, scientifically grounded definition of the specific plant-based research parameters subject to or exempt from this policy.
h. The draft exempts or modifies review criteria for research involving "well-characterized cell lines" but fails to define the term or outline its scope. It remains unclear whether this scope is limited to common mammalian systems, or extends to insects, fish, yeast, or other eukaryotic cell models. NIH should establish a precise, scientifically valid definition of what qualifies

a cell line as "well-characterized," detailing the taxonomic boundaries and specific safety data required to achieve this status.

i. The proposed policy lacks an explicit framework governing Dual Use Research of Concern (DURC), Gain-of-Function (GOF) research, or high-consequence biosecurity parameters. Omitting these critical oversight pillars represents a severe regression from established federal biosafety standard operating procedures. NIH should integrate a clear, risk-stratified biosecurity framework that explicitly harmonizes with existing United States Government (USG) policies on DURC and enhanced Potential Pandemic Pathogens (ePPP).

j. The policy fails to recognize or regulate artificial intelligence (AI) biological design tools. Crucially, the draft provides no framework for reviewing, registering, or containing constructs where the evolutionary or biological "parent organism" has been completely obscured by algorithmic, de novo design. NIH should formulate oversight criteria specifically addressing de novo designed sequences, mandating functional risk assessments for constructs where taxonomy-based classification is impossible due to AI design.

k. The draft creates a significant biosecurity loophole by disregarding regulatory standards for DNA design, gene synthesis screening, and mass-produced synthetic libraries of gRNA/DNA. NIH should codify mandatory synthesis screening alignment protocols for institutions acquiring or producing synthetic genetic materials and guide libraries.

l. The policy is written strictly through the lens of traditional cellular biology, failing to mention or regulate cell-free translation/transcription systems. Furthermore, it completely overlooks mirror-image biology, synthetic or non-natural amino acids, and xenobiological nucleic acids (XNA). NIH should expand the definitions to account for cell-free synthesis of hazardous toxins or agents and establish clear risk boundaries for synthetic life forms utilizing non-standard genetic codes or non-natural amino acids.

m. The draft policy states, "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." However, the draft policy does not include explicit rules about how this would work or what the impact would be on other NIH-funded research at the same institution if NIH determines that the other agency does not meet NIH requirements. NIH should more explicitly

set forth guidelines for research under the regulation or purview of other federal agencies.

2. *Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).*
    a. Delegation pathways under this policy are poorly bounded. Section IV-3 permits protocol review to be "delegated to an individual or a subgroup of IBC members," and notes functions can run through "[t]he IBC, or its delegate as applicable." The draft fails to specify what qualifies an individual to approve biological research, or who holds the authority to grant that delegation. NIH should explicitly prohibit the unilateral approval of biological protocols by a single individual. NIH should define competency and credential requirements for any subcommittee or individual delegate to perform preliminary reviews on behalf of the full IBC.
    b. While the Principal Investigator (PI), Biosafety Officer (BSO), and IBC are all individually tasked with conducting risk assessments, the draft policy contains no guidance on how to integrate these assessments or resolve technical conflicts among the PI and the institutional biosafety review bodies. Furthermore, the draft policy states that "low-risk transgenes" dictate whether review delegation is permitted, but leaves "low-risk" undefined. NIH should explicitly detail the hierarchical workflow for risk assessments, establishing that the local BSO/IBC holds final authority over risk classification. NIH should provide a clear, objective definition for "low-risk" transgenes based on functional traits (e.g., non-toxigenic, non-pathogenic, replication-incompetent).
    c. The mandate that, "No research subject to this Policy may be conducted until the institution…has provided a written Biosafety Assurance through the Authorized Organizational Representative (AOR) that has been approved by NIH" will cause operational delays across the research enterprise. NIH should restructure this provision to utilize a risk-stratified approach. NIH should reserve mandatory prior NIH approval strictly for high-consequence research, such as Gain-of-Function (GOF), Dual Use Research of Concern (DURC), and Institutional Review Entity Oversight of Functional Cloning (IROFC). Standard low-to-moderate risk research should proceed under local IBC approval with routine NIH registration.
    d. Requiring institutions to "petition" the NIH to determine containment for emerging, novel, or zoonotic agents – or to lower containment for Risk Group (RG) 3 or RG4 agents – bypasses the primary function of the BSO and IBC. Local biosafety programs are fully equipped and structurally designed to perform these exact agent risk assessments. NIH should authorize the local

BSO and IBC to determine containment levels via comprehensive, documented risk assessments that consult peer-reviewed literature, historical data, and established regulatory frameworks. The NIH should provide guidance and reference criteria rather than acting as a mandatory approval bottleneck.

e. Limiting the mandatory appointment of a BSO only to institutions operating at Biosafety Level (BSL)-3/4 or working with Gene Drive Modified Organisms (GDMOs) is short-sighted. A BSO is essential for managing the foundational safety architecture to include BSL-1 and BSL-2 facilities. Furthermore, the draft policy positions the BSO as a passive auditor who merely reviews if "IBC approval conditions…are being followed," eroding the modern collaborative unit of the IBC and biosafety program. NIH should amend the policy to require a designated BSO for any institution conducting research subject to this policy, regardless of the BSL classification. NIH also should revise the language to formalize a synergistic relationship where the BSO and the IBC act as co-equal partners in developing, executing, and monitoring institutional biological risk management controls.
f. The requirement for the NIH to determine containment for emerging, novel, or zoonotic agents absent from the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual is infeasible. The BMBL is not exhaustive. Furthermore, the repeated use of the phrase "timely manner" regarding NIH containment reviews introduces extreme administrative vulnerability. NIH should explicitly state that the BMBL is a foundational guide, but not an all-encompassing regulatory ceiling. NIH should empower local BSOs and IBCs to utilize peer-reviewed literature to determine containment via local work planning and controls. NIH should define precise timelines (e.g., "within 15 business days of receipt") for every segment where NIH review or response is mandated.
g. The tasks outlined in Section V, V-A, and V-D represent the daily operational realities of work planning and engineering controls. These are handled dynamically by the BSO and the biosafety program, not through the episodic meeting schedule of an IBC. NIH should reassign the active oversight and validation of work planning controls to the local BSO, with retrospective or periodic oversight provided by the IBC.
h. The text in Section V-E accurately notes that Risk Groups (RGs) and BSLs are related but not equivalent, allowing containment to be adjusted higher or lower based on specific manipulations. However, this fluid risk-assessment philosophy directly contradicts the rigid, centralized NIH approval mandates

established earlier in the draft. NIH should maintain the scientifically sound logic of Section V-E. NIH should harmonize the rest of the draft policy to align with this philosophy by trusting local BSOs and IBCs to fluidly adjust BSLs up or down based on their localized, comprehensive biological risk assessments.

3. *Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).*
    a. Battelle PNWD has no comment on this RFI.
4. *Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).*
    a. Battelle PNWD has no comment on this RFI.
5. *Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.*
    a. While the provision protecting voluntarily submitted "near-miss" data from enforcement or funding actions is excellent, recommending institutions to submit this data directly to an enforcement entity like the NIH will stifle participation. NIH should restructure this framework so that near-miss and procedural data are submitted to an independent, neutral third-party scientific repository rather than the NIH directly, ensuring absolute anonymity to foster a robust culture of safety reporting.
    b. The phrase, "Any incidents involving exposures at BSL-2/ABSL-2 that require agent-specific treatment beyond basic first aid" is highly ambiguous and open to interpretations across institutions. NIH should provide clear, concrete examples of what constitutes "agent-specific treatment" versus standard medical countermeasures to ensure uniform reporting compliance.
    c. The draft policy requires that IBC meeting minutes and incident reports must be publicly posted for a minimum of five years. The draft minutes template and the draft incident reporting template require institutions to provide detailed information, yet the instructions for each form only allow redactions for private or proprietary information, without taking into account the potentially serious adverse impact to an institution's operational security from posting the required level of detail. NIH should allow institutions to redact or withhold information based on the institution's assessment of security risk, including allowing redaction of Controlled Unclassified Information (CUI) and export-controlled information. Additionally, NIH should allow biosecurity incidents to be reported through existing security channels, rather than requiring that they be posted publicly.

6. *Feedback on the implementation resources and areas in which additional guidance would be beneficial*.
    a. The text relies heavily on vague qualifiers such as "certain," "as appropriate," "as applicable," "as needed," and "as warranted" throughout the entire document. This vague terminology shifts the burden of interpretation onto institutions without providing clear criteria governing those interpretations. For example, Section III-A states, "This responsibility may be delegated to the BSO or other staff, as appropriate." The draft policy permits delegation of research compliance reviews but provides no guidance on what qualifications make delegation "appropriate." Similarly, Section IV states, "Certain research associated with higher levels of risk or uncertainty must be reviewed and approved at the Federal level by NIH." The word "certain" provides no guidance regarding what type of research must be approved by NIH. NIH should strike all subjective terms and replace them with objective criteria stating exactly when, why, and under what precise metrics an action is required or permitted.
    b. While training is mandated in the abstract, the draft provides no minimum competency standards, core curricula, evaluation metrics, or mandatory training subjects. NIH should delineate the baseline, mandatory core competencies and subject areas required for PIs, laboratory staff, and IBC members to ensure uniform training efficacy.
    c. The requirement to publicly post institutional biosafety procedures explicitly detailing BSL-3/ABSL-3 or BSL-4/ABSL-4 capabilities, alongside research with GDMOs, draws unnecessary and potentially hazardous public attention to secure facilities. NIH should strike the mandatory public listing of high-containment asset locations to protect facility security and biosecurity integrity. NIH should replace all open-ended phrasing with a specific list of required disclosures.
    d. Requiring PIs to submit initial protocols and subsequent minor modifications to both the IBC and the NIH for approval is not consistent with operational reality. It will cripple project timelines and incentivize non-compliance. NIH should re-establish that protocol review and approval is the responsibility of the PI, BSO, and/or IBC. Submission of initial and modified protocols to NIH for approval should be eliminated.
    e. The draft policy states that PIs must ensure the "integrity, maintenance, and correct functioning of facilities [and] physical containment equipment." A PI does not possess the operational authority or expertise to maintain facility HVAC systems, HEPA filtration, or structural integrity; this is an institutional

function. NIH should amend this portion of the text to state that PIs are responsible for *reporting* facility and equipment defects immediately, while the *institution* is responsible for ensuring the ongoing integrity, maintenance, and certification of facilities and engineering controls.

f. Will approvals be required only upon receipt of notice of award or as part of the grant submission process? Should institutional approval precede NIH approval?

g. The draft policy proposes that institutions submit voluntary, confidential reports regarding near misses, secondary failures, or procedural issues to the National Biosafety Data and Safety Analysis Center (NBDSAC), and states that data maintained within the NBDSAC repository will be de-identified to protect individual and institutional privacy. NIH should provide additional information about the proposed NBDSAC, including who operates it, what level of information it will be authorized to receive (CUI, classified, etc.), and whether the data in the aggregate will be reviewed for information and operational security concerns.

Conclusion

In summary, Battelle PNWD's review of the draft policy identified several general themes:

- **Reduced clarity:** While the existing *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2024)* provide explicit, detailed definitions and clear boundaries for institutional oversight, the draft policy shifts away from regulatory precision. Rather than enhancing biological safety, this draft introduces systemic ambiguity, structural loopholes, and phrasing that leaves compliance obligations open to interpretation by each research institution.
- **Risk of systemic delays:** Multiple provisions requiring direct NIH review and approval for standard oversight mechanisms (e.g., Biosafety Assurances, containment downgrades) will create severe administrative bottlenecks, delaying or even preventing research of national importance. These requirements fail to leverage the existing infrastructure of local Institutional Biosafety Committees (IBCs) and Biosafety Officers (BSOs).
- **Erosion of local authority:** The draft policy consistently shifts the responsibility of risk assessment and containment determination away from local Subject Matter Experts (SMEs)—specifically BSOs and IBCs—and centralizes it within the NIH. This undermines the established principle of institutional self-governance via local peer review.
- **Omission of frontier biotechnologies:** The draft policy fails to account for cutting-edge technologies, completely omitting regulatory frameworks for AI-generated biological design, synthetic DNA screening, cell-free systems, and non-natural/mirror-image biology.

NIH should revise the draft policy to provide more clarity, consistency, and forward thinking while preserving institutional self-governance and process efficiency to safely advance necessary, groundbreaking research.

Battelle PNWD appreciates the opportunity to provide these comments and recommendations.

258. Martin Pavelka

I am responding: On behalf of myself

Name: Martin Pavelka

Name of Organization: University of Rochester

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Bacteriology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Since the questions asked are different, our IBC has always used the RGs run the Guidelines as they pertain to recombinant work, but defer to the BMBL for assessment for non-recombinant work.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft states "Institutions must report to NIH incidents involving…. any incident at BSL/ABSL-3 or BSL/ABSL-4 (including
potential exposures)". "Any incident" seems too broad and ill-defined. What does this mean, beyond potential exposures or overt exposures?

The draft states "Delete NIH incident reports for incidents at BSL-1/ABSL-1, BSL-2/ABSL-2 that do not involve agent-specific medical treatment when first aid is administered". I'm not sure that it will be possible to determine what specific treatments the person received due to HIPAA restrictions.

6. Other feedback relevant to this resource: N/A

259. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1 Clarify which genetically modified materials require full IBC review. The proposed language for “genetically modified cells, viruses, or organisms” is too broad without definitions or examples, especially for “certain vectors, replicons, gene drive modified biological agents, GDMOs”. NIH should provide clear risk-based criteria, so routine low-risk molecular biology, standard non-replicating vectors, or established low-risk systems are not unnecessarily routed to full committee review.

2. Exempt low-risk, non-replicating synthetic nucleic acids, synthetic oligonucleotides, and certain transgenic animals from registration unless they encode hazardous products. The Policy should explicitly exempt low-risk, non-replicating synthetic nucleic acids and synthetic oligonucleotides, as well as transgenic animals maintained at BSL-1/ABSL-1, from IBC registration. Transgenic animals should qualify for the exemption only when genetic modification does not encode a hazardous product or otherwise meaningfully increase biosafety, occupational health, animal, environmental, or public health risk. Requiring registration for very low-risk nucleic acids and modified animal models creates unnecessary administrative work for investigators and compliance offices, including repeated alignment and amendment of IBC and IACUC protocols, without a corresponding biosafety benefit.

3. Define which toxins are within the scope of the Policy. The current NIH Guidelines define toxins within scope as those having an LD50 of less than 100 ng/kg. The draft NIH Biosafety Policy does not establish a potency threshold or otherwise define which toxins are covered, creating uncertainty about which proteins require IBC approval before use.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support the Policy’s risk-based approach, including the option for delegated review of low-risk research.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1. Balance transparency with biosecurity. NIH should require institutional accountability without mandating public disclosure of sensitive technical details. Institutions should retain complete IBC minutes and incident records for NIH or other authorized oversight bodies, while public summaries should provide non-sensitive information sufficient to demonstrate oversight.

2. Reduce the detail required in the NIH IBC meeting-minutes template. The template should support concise public summaries without requiring agent-specific methods, facility vulnerabilities, security-sensitive deliberations, detailed incident narratives, or construct details. Even when this information is not proprietary, publicly posting it could reveal researchers planned work to competitors worldwide before the research begins.

3. Incident reporting and public posting of minutes may have unintended consequences: PIs and other personnel may be less likely to report incidents if they know the information could be posted publicly on the institution's website. In some cases, identifying the PI and agent involved could allow readers to figure out who the person is in an exposure or infection report, creating potential privacy concerns. There is also concern from an IACUC perspective of releasing animal care-related details into public forum (relevant for both minutes and incident reports). A more appropriate approach would be to report incidents to NIH, which could aggregate and evaluate the information and publish de-identified reports for the public.

4. Define which inspection findings must be reported. NIH should provide clear, risk-based criteria and examples distinguishing reportable findings from routine deficiencies that institutions can correct through normal follow-up. Guidance should address common findings such as missed eyewash inspections, incomplete personal protective equipment use, training lapses, documentation deficiencies, equipment certification issues, and containment failures. Reporting should focus on findings that present a significant or unresolved risk to personnel, the environment, or public health rather than minor issues that are promptly corrected.

6. Other feedback relevant to this resource: 1. Provide examples and exemptions to support consistent implementation. Practical examples would help institutions distinguish among activities requiring full IBC review, delegated review, registration, or no registration. NIH should address common areas of uncertainty, including viral vectors, replicons, genetically modified cells, low-risk transgenic animals, and low-risk recombinant or synthetic nucleic acid research (for example, overexpression plasmids encoding nonhazardous human proteins). Requiring IBC review for every nonhazardous gene or construct would add work for investigators, biosafety offices, and IBCs without improving biosafety.

2. Clarify transition requirements for protocols approved for more than three years. NIH should explain how the new Policy applies to active protocols with approval periods that extend beyond the proposed three-year limit. Institutions need to know whether these protocols must undergo renewed review by the Policy's implementation date, be reviewed within three years after that date, or remain approved until their current expiration dates. NIH should also clarify how institutions should handle active

protocols involving agents that were previously exempt from IBC registration. Clear transition requirements and a reasonable implementation period are needed to ensure consistent compliance and avoid unnecessary disruption of ongoing research.

3. Provide practical tools and examples for conducting appropriate risk assessments. Institutions establishing new IBCs may have limited experience conducting in-depth risk assessments or may not have systems for collecting the necessary information from PIs. NIH should provide risk-assessment templates, examples, and training resources to help these institutions develop consistent processes and prepare new IBC members to conduct appropriate reviews.

4. Allow sufficient time for approval of Institutional Assurances before Policy implementation. Institutions that were not previously required to register an IBC may need to establish institutional policies and procedures, create a new committee structure, develop systems to collect the required information, prepare an Institutional Assurance, and obtain NIH approval. Completing these steps within the six months between Policy finalization and implementation would be extremely difficult. The same timeline may also be challenging for established institutions whose IBCs already review recombinant and wild-type agents. NIH should provide an implementation period that reflects the time required for institutions to establish or revise these systems and obtain approval (at least 1-2 years).

260. James H. Doudna Cate

I am responding: On behalf of myself

Name: James H. Doudna Cate

Name of Organization: N/A

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Molecular biology, chemical biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112, contains a nonscientific definition of "genetic modification". Specifically, the definition of "genetic modification" includes: "The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria: ..." One of the criteria listed is "Can be transcribed or translated." This is utter nonsense. For example, transient transfection into mammalian cells of a plasmid encoding the protein Green Fluorescent Protein (GFP) would be considered a genetic modification, even though both the plasmid and the resulting GFP protein will disappear from the cells or organism in a matter of days. There is no permanent change to the genome of the cells or organisms in this case. Even with selective pressure such as antibiotics, removal of the selective pressure will lead to loss of the plasmid over a short period of time, again days. The proper definition of "genetic modification" must include a permanent change to the genome of the cells, organisms, or viruses. The definition in NOT-OD-26-112 goes against decades of understanding of molecular biology.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Given the improper definition of "genetic modification" as described in answer 1, the utility of Risk Groups will be compromised.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Description: Comment on nonsensical definition of "genetic modification" in NOT-OD-26-112

261. Amptiv Biosciences

I am responding: On behalf of an organization

Name: Jon Bell

Name of Organization: Amptiv Biosciences

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definition of genetic modification is incorrect. The use of 'can be transcribed or translated' will incorrectly include therapeutic modalities that have nothing to do with genetic modification such as mRNA, saRNA, and episomal DNA.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

262. Mr. M

I am responding: On behalf of myself

Name: Mr. M

Name of Organization: University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As an ABSA member and ABSA CBSP, I support the following organizational response to the proposed NIH Biosafety Policy for Research Involving Biohazards. See attached letter.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 261014-ABSA-NIH-Biosafety-Policy-Comments.pdf

Description: As an ABSA member and ABSA CBSP, I support the following organizational response to the proposed NIH Biosafety Policy for Research Involving Biohazards. See attached letter.

ABSA International — The Association for Biosafety and Biosecurity

Organization:	ABSA International 1200 Allanson Road, Mundelein, IL 60060 Phone: (866) 425-1365 | Email: info@absa.org | Web: www.absa.org
Date:	October 19, 2026
To:	Office of Science Policy National Institutes of Health 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892
Submission Portal:	Submitted via NIH OSP Electronic Comment Portal
Subject / Notice:	Formal Public Comments and Recommendations on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice Number: NOT-OD-26-112)

ABSA International, the Association for Biosafety and Biosecurity, is a nonprofit professional association representing biosafety and biosecurity professionals in the United States and internationally. Our membership spans academic and research institutions, government laboratories, biotechnology companies, healthcare organizations, public health agencies, and consulting practices. Members bring scientific, technical, operational, and regulatory expertise across diverse biological research and laboratory settings.

ABSA's comments reflect the practical experience of professionals responsible for translating biosafety policy into daily practice. Our members conduct risk assessments, support Institutional Biosafety Committees (IBCs), develop training and containment practices, investigate incidents, and advise institutions on compliance. They understand how policy requirements affect laboratory safety, reporting culture, institutional resources, and the conduct of research.

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public

confidence in NIH-supported science. ABSA supports NIH's efforts to strengthen biosafety oversight. We offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

***Topic to Address**: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:

    a. the nature and stability of the genomic modification;

    b. whether the modification is heritable and the potential for transmission through breeding;

    c. effects on animal health, phenotype, host range, susceptibility, or disease;

    d. potential entry into breeding or food-production systems;

    e. potential environmental release or interaction with non-research animal populations;

    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and

    g. applicable federal, state, or other regulatory oversight.

2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

  Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

ABSA International believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, ABSA International requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, ABSA International welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. ABSA International does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. ABSA International recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, ABSA International recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with ABSA's earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. ABSA International recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, ABSA International kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. ABSA International encourages NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While ABSA supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: ABSA recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

263. Upstate Biosafety, LLC

I am responding: On behalf of an organization

Name: David Pawlowski

Name of Organization: Upstate Biosafety, LLC

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosafety Consulting

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of this policy is appropriate and will align most IBCs with what is already happening at many institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered oversight is appropriate and gives local IBCs freedom to set research oversight using their own risk assessments.

3. Continued utility of Risk Groups: The use of Risk Groups is preferred and allows for oversight based on risk assessment, Risk grouping, procedures, engineering controls, and staff proficiency.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I'm happy that a statement on voluntary compliance was included.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached document for specific comments. Imperative to the reporting template, names should be removed as this will harm the open culture of safety that is being developed throughout so many institutions.

6. Other feedback relevant to this resource: see attached document

Uploaded File: NIH-Biosafety-policy-Comments.docx

Upstate Biosafety, LLC Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Notice NOT-OD-26-112 ·

The Modernization of the NIH guidelines is well a supported effort. The draft NIH Biosafety policy is a well written document that places local risk assessment to the forefront of the policy, which is a very welcome aspect of the document. I very much appreciate all of the effort that has gone into creating this draft, especially the regional listening sessions and the ability to comment on the policy prior to its adoption. Please accept the comments below for thoughtful revision of this exciting draft policy.

High-priority comments

Draft policy

ID	Section / item	Comment	Suggested change
P-001	Section II - Scope	The draft includes "Research conducted with transgenic organisms at BSL-1/ABSL-1", which may be interpreted as any research with transgenic rodents for example including breeding.	Clarify the scope of research with established transgenic rodents and other animals
P-002	Section II - Scope	Novel agent or organism: An agent or organism not existing in nature, deliberately designed, and possibly derived from multiple, different natural or synthetic sources (e.g., chimeras, or organisms generated by synthetic biology in conjunction with artificial intelligence).	Clarify if this means reviewing the software or how the AI is used. Prepare tools and guidance on how to review AI. With AI, there are no organisms, physical infrastructure ext. Provide guidance on how institutions audit this area of research.
P-003	Section II - Scope	Creating a de novo biosafety registration every three years creates an administrative burden and diverts resources.	Recommend a triennial review, thus aligning with IACUC and IRB rules.
P-004	Section II - Scope	The scope of "self-aggregating proteins" needs to be clarified. Does this mean misfolded, self-aggregating proteins or all self-aggregating proteins that are normal biology?	Clarify for “hazardous” self-aggregating proteins versus “all” self-aggregating proteins
P-005	Section II - Scope	The definition of cells, viruses, or organisms that have been genetically modified does not clearly indicate if breeding of transgenic rodents, (previously exempt) is now covered by the new policy	Clearly define if breeding of previously exempt transgenic animals is still exempt
P-006	Section II - Scope	The existing scope of NIH Guidelines extends to clinical trials conducted with gene transfer products produced with NIH funding. For example, when an academic medical center develops a product with NIH funding, a clinical trial of that product may	The current scope of applicability for clinical trials as long as research collaboration or contractual agreements exist should be preserved for any new policy. Licensing of a product or technology to a business entity should not abrogate biosafety requirements.

ID	Section / item	Comment	Suggested change
		be conducted at the originating institution and also at community clinics. Under current rules such clinical trials require IBC oversight at all locations in the USA as long as research collaboration or contractual agreements apply. This means that staff, visitors, and the public near the community site have equal and equitable protection of IBC oversight compared to staff and visitors at the academic medical center.	
P-007	Section II - Scope	The Draft Policy proposes that research "also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained" This sentence could be construed to limit the scope of the Draft Policy to the point of irrelevancy. There are innumerable federal agencies and any research in the USA is also under the regulation or purview of multiple agencies such as OSHA, EPA, CDC, and / or EEOC.	Simply being under purview of multiple agencies should not exempt research from IBC oversight.
P-008	Section II Scope	As written, the definition of "research involving biohazards" provided under Scope does not make it clear that the "potential risk to human health" is from the biohazardous materials by saying "involving known or potential risk to human health AND any of the following....". Technically, the potential risk to human health could be from a chemical or radiological hazard using this definition.	One option to address this would be to replace "and any of the following" with "attributed to any of the following". However, the term "Biohazard" should be clearly defined under General Definitions.
P-009	Section II - Scope	The draft defines biohazards primarily in terms of risks to human health, which may exclude biological agents that pose significant risks to animal health, plant health, agriculture, or the environment. This may create gaps compared with the current NIH Guidelines.	Clarify whether animal, plant, agricultural, and environmental biohazards are within the scope of the Policy. If they are intentionally excluded, clearly state this and explain how the existing plant and environmental biosafety provisions of the NIH Guidelines will be addressed under the new framework.
P-010	Section II - Scope	The inclusion of "clinical settings" within laboratory research creates uncertainty as to whether routine collection of human biospecimens for research, such as venipuncture, requires IBC oversight even when no biohazard is manipulated or administered.	Clarify that routine clinical specimen collection alone does or does not require IBC review solely because specimens are collected for research. Subsequent handling or manipulation of the specimens should be evaluated separately based on the associated biosafety risk.
P-011	Section II - Scope	The definition of "biomedical research in laboratory settings" does not clearly address biosafety-relevant field research or non-research biological activities, such as	Clarify that field research involving meaningful biological exposure risks, such as wildlife handling or sampling with potential zoonotic hazards, should receive appropriate

ID	Section / item	Comment	Suggested change
		teaching laboratories in academic institutions. This may create both gaps in oversight and unnecessary expansion of IBC requirements.	risk-based biosafety oversight. Conversely, clarify if teaching laboratories and other non-research activities should be subject to the Policy.
P-012	Section II - Scope	The proposed six-month implementation period may be insufficient given the substantial changes in institutional responsibilities, oversight processes, training, procedures, and compliance systems required by the new Policy.	Provide at least 12 months between publication of the final Policy and its effective date to allow institutions sufficient time for effective and consistent implementation.
P-013	Section II - Scope	Clarify if "clinical settings" includes routine pathology lab work where the data collected from clinical specimens (e.g. bacterial cultures, etc.) will be analyzed for research. As written, virtually all clinical pathology laboratories which contribute to research would now require IBC oversight.	Specify that [certified, accredited, etc.] clinical laboratories which contribute to research through performing routine procedures are not subject to IBC oversight.
P-014	Section II - Scope	The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition.	Distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.
P-015	Section II - General definitions	On the proposed definition of Genetic Modification, with regard to passaging for example this would encompass almost all cell biology. Any passaged cell in cell culture will undergo some stable alteration, albeit non-deliberate and non-targeted.	The definition of Genetic Modification can be limited to deliberate modifications including passage under one or more selective pressures.
P-016	Section II - General definitions	The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. The draft also refers to gene drive modified organisms, gene drive modified biological agents, and GDMOs without reconciling the terms.	Biological agent definition in 18 USC 178 (1) should be consistent throughout all government documents
P-017	Section II - General definitions	The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk.	Distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis, and assign oversight based on the resulting or expected phenotype and risk.

ID	Section / item	Comment	Suggested change
P-018	Section III-A - Responsibilities of the Institution	The Policy does not clearly define what constitutes an adequate OHSP for research subject to the Policy or how institutions should determine and document that the OHSP appropriately addresses the relevant research risks.	Clarify that an existing institutional OHSP may satisfy the Policy if it appropriately covers the applicable research and associated hazards. NIH should also provide criteria or guidance for institutions to assess, review, and document the adequacy of occupational health support for research subject to the Policy.
P-019	Section III-A - Responsibilities of the Institution	Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for the researchers involved, where identification, even generally, could put their personal safety at risk.	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries focused on oversight outcomes, corrective actions, and lessons learned. Detailed records would remain available to NIH for oversight and through existing lawful disclosure processes.
P-020	Section III-A - Responsibilities of the Institution	Biosafety Assurance approval is required before covered research can continue, and NIH review may not be complete on the effective date.	Provide a transition mechanism for Biosafety Assurance approval, such as provisional or deemed assurance, so ongoing covered research is not halted because NIH review is incomplete on the effective date.
P-021	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The term "release" needs to be better defined involving facility and/or equipment failures. This term has caused confusion in the past, is this term being defined as a breach in primary containment, or otherwise?	Better define or change term "release" to change to true intent of meaning, whether that be a breach or primary containment or otherwise
P-022	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Criteria for determining a "potential laboratory-acquired infection" under the report requirements are not provided.	Provide specific criteria for what would be considered a "potential laboratory acquired infection" or revise to limit the reporting requirement to confirmed laboratory-acquired infections through diagnostic testing given the time sensitive reporting requirement for 24 hours.
P-023	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The reporting expectations for "compliance violations" at any BSL/ABSL is vague and open ended. This reporting expectation needs to be specific to avoid over reporting of minor compliance issues.	Revise the compliance violation reporting statement to be specific as follows: The following compliance violations associated with this policy at any BSL/ABSL/ACL: 1) Failure to obtain or maintain IBC approval; or 2) Failure to obtain NIH approval for lowering biocontainment for research, when required.
P-024	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The expectation to include or have access to an individual knowledgeable in “community attitudes” appears to overlap with the required unaffiliated IBC members, who are specifically appointed to represent	Clarify whether the required unaffiliated community members ordinarily satisfy the “community attitudes” expectation, or whether NIH intends this to represent a

ID	Section / item	Comment	Suggested change
		the interests of the surrounding community.	separate area of expertise requiring an additional member or ad hoc consultant.
P-025	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft primarily describes the BSO through operational and technical duties and does not fully reflect the BSO's broader role in institutional biosafety governance. It also does not clearly address the authority, leadership access, and resources necessary for the BSO to effectively fulfill these responsibilities.	Define the BSO as the institution's designated biosafety professional responsible for leading or administering the biosafety program and providing technical oversight. Require appropriate authority, access to institutional leadership, and resources, and clarify that operational functions may be delegated to qualified biosafety professionals under the BSO's direction or supervision.
P-026	Section III -B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft does not require a BSO unless a certain biosafety level of research is occurring. This can create an undue burden on already stretched faculty and/or a conflict of interest	Consider the following; all R1 Universities should have a full-time professional BSO.
P-027	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The policy expands BSO and IBC responsibilities without defining corresponding authority.	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support: access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary. Specify the authority, independence, and access expected for a BSO or alternate official performing BSO duties.
P-028	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft ties public posting of final incident reports to NIH's "final response," but does not define an endpoint for that response, so institutions could be held to a posting deadline that depends on an open-ended federal review. The draft also does not state what may be redacted.	Establish a defined endpoint for NIH's "final response." If public posting is retained, define allowable and required redactions, including PI names, grant identifiers, and other information needed to protect proprietary and security-sensitive information, and replace detailed public disclosures with de-identified summaries wherever possible.
P-029	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The incident reporting categories overlap and use undefined terms. It is unclear whether precautionary post-exposure prophylactic treatment is "agent-specific treatment," whether any event at BSL-3 or BSL-4 is reportable regardless of its relevance to biohazard containment, and how administrative noncompliance differs from events presenting an actual biosafety risk.	Define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." Clarify the points above, and do not require a 24-hour reporting timeframe for administrative noncompliance and other low-risk items.
P-030	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Requiring every internally reviewed minor event to be publicly posted with unredacted identifying information would undercut local management of lower-risk events and near misses.	Preserve local management of lower-risk events: institutions should retain authority to manage lower-risk events and near misses through local IBC review systems. Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events,

ID	Section / item	Comment	Suggested change
			minor spills, and compliance violations that do not present a meaningful safety risk.
P-031	Section III-D - Responsibilities of the National Institutes of Health (NIH)	The draft anticipates NIH publication of approved lower-containment determinations but does not state whether another institution may rely on them.	Create a searchable national determination and risk-classification database. Define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies, so that a prior NIH containment determination may be used by another institution without a new petition.
P-032	Section III-D - Responsibilities of the National Institutes of Health (NIH)	Public posting of incident report information may inadvertently allow identification of the individual(s) involved, potentially violating federal rules on disclosure of medical information. A national system is only useful if its boundaries are clear and if institutions and researchers trust that voluntary submissions will not be used for enforcement.	Develop a confidential, de-identified national reporting system that supports trend analysis and shared learning, preserves confidential near-miss reporting, and states that voluntary submissions will not be used for enforcement. Publish annual de-identified summaries, trends, contributing factors, and lessons learned, without attaching names or institutions to routine, well-managed incidents.
P-033	Section IV - Categories of Oversight for Research Based on Risk	The policy is unclear regarding review of synthetic/recombinant DNA. Research with plasmids or viral vectors appears to be covered under IV-3, but synthetic nucleic acids do not appear to be covered in the new policy.	Better define research with synthetic nucleic acids
P-034	Section IV-1 - Research That Requires NIH and IBC Approval Before Initiation	Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently handled routinely at both BL1 and BL2, for example organisms discovered during environmental screens.	Define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.
P-035	Section IV-2 - Research That Requires IBC Review and Approval Before Initiation	For clinical research, "capable of shedding" is very vague. Is shedding assumed unless there is evidence otherwise? Must the evidence be agent-specific (those data usually don't exist), or can it be categorical? What constitutes shedding - viable agent or identifiable fragments (many studies only use PCR to look for fragments)? The scope will vary dramatically based on those answers.	Clarify criteria for what constitutes shedding under the intent of the Policy.
P-036	Section V-A - Requirements and Considerations for Risk Assessment of the Characteristics of the Biohazard	The statement under Section V-A that "Biological agents that cause disease in humans are classified into four RGs based on pathogen characteristics and population impacts." is incorrect. The current definition of risk groups in the NIH	Revise the statement "Biological agents that cause disease in humans are classified into four RGs based on pathogen characteristics and population impacts." to reflect NIH's revised classification system for effectively characterizing societal risk vs. worker risk.

ID	Section / item	Comment	Suggested change
		Guidelines provides no reference to community risk or population impact. Although the WHO definition of risk groups does make an effort to include community risk, the relative community risk assigned to each risk-group does not adequately capture the large variations in community/population risk that exists at each human health-based RG category. For example, Appendix G of the NIH Guidelines defines BSL-3 enhanced requirements for specific RG3 influenza viruses based largely on their pandemic potential, which is not at all consistent with the WHO RG3 characterization of community risk as "low community hazard" and "does not ordinarily spread from one individual to another". Given this important discrepancy between risk group classifications and societal risks, NIH needs to consider creating a separate, distinct risk classification nomenclature specific to relative societal risk.	
P-037	Section V-D - Requirements and Considerations for Risk Assessment of Manipulations of Biohazards	The Policy identifies “large culture volumes” as a factor that may increase risk but does not define what constitutes a large volume or when additional large-scale risk assessment is expected.	Define a threshold or clear criteria for identifying large-volume culture research based on organism and procedural risk.
P-038	Section V-E - Risk Mitigation Strategies and Laboratory Containment	The requirement for conducting experiments with viruses containing genes from RG3 influenza viruses with pandemic potential at BSL-3 enhanced containment with the additional requirement for an occupational health plan does not specify the detailed expectations of the minimum BSL-3 enhanced requirements. The Background section of the policy does note that additional information about requirements for containment practices, occupational health plans, and training for research with RG3 influenza viruses (currently articulated in Section II-D-7 and Appendix G-II-C-5 of the NIH Guidelines) will be shared with the research community through implementation resources. However, there needs to be a clear minimum set of requirements when it comes to BSL-3 enhanced expectations for RG3 influenza viruses and other pathogens with potential for significant societal consequence. These expectations should be the default mitigation measures unless a specific element is determined to be	Ensure that the BSL-3 enhanced mitigation measures planned to be included in the implementation resources serve as the default requirements for BSL-3 enhanced for RG3 influenza viruses and other communicable pathogens with potential for significant societal consequence, unless otherwise determined to be unnecessary by the local IBC in consultation with NIH.

ID	Section / item	Comment	Suggested change
		unnecessary based on the IBC risk assessment of the agent and protocols involved.	
P-039	Section V-E - Risk Mitigation Strategies and Laboratory Containment	The draft requires BSL-3 enhanced containment and an occupational health plan for specified influenza research but does not define the minimum requirements for either, creating uncertainty in implementation and compliance.	Define the minimum requirements for BSL-3 enhanced containment and the influenza-specific occupational health plan or directly reference applicable implementation guidance. Also clarify how the required occupational health plan relates to the institution's broader occupational health and safety program.
P-040	Other Comments	The Policy relies heavily on headings and bullet points, making specific provisions difficult to cite and cross-reference consistently	Adopt a consistent hierarchical numbering system and assign each substantive requirement a stable, unique citation identifier (e.g., III.B.2.a.(1))
P-041	Other Comments	The policy does not define a location for responsibility. Are tenants of a location the responsibility of the IBC serving that location or are tenants responsible for obtaining IBC support elsewhere.	Define who is responsible for oversight in leased space situations.

Draft incident reporting template

ID	Section / item	Comment	Suggested change
I-001	Part 1. Institutional Information	All reports for incidents must be posted on a public-facing webpage of the institution.	**Suggestion 1:** A strong safety culture depends on researchers feeling comfortable with reporting incidents, near misses, and unsafe conditions without fear the report will be considered punitive. Public posting of incidents could lead to fear that the report could be used to blame labs and create a negative mind set, leading labs to be more reluctant to report incidents. **Suggestion 2:** Many incidents that would fall under this are minor, and posting everything would not serve the public interest and would dilute attention from potentially significant incidents. For example, incidents involving noninfected lab mice are categorically different than incidents involving pathogen cultures.
I-002	Other Comments	The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially violating federal rules on disclosure of medical information.	**Revise the template and posting requirements so that required fields cannot identify the individuals involved; use de-identified, aggregate public reporting (see P-102).**

Medium priority comments (41)

Draft policy (35)

ID	Section / item	Comment	Suggested change
P-042	Section II - Scope	Definition for Synthetic Nucleic Acids is missing	Add the definition of SNA used in the current NIH Guidelines: nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (mRNA, miRNA)
P-043	Section II - Scope	Work with genetically modified arthropods is not presented in the scope section	Add example to "Cells, viruses, or organisms (for example arthropods), other than plants, that have been genetically modified;
P-044	Section II Scope	It's not clear what is meant by the statement, "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained."	Revise statement to say, "once approvals or other applicable clearances have been obtained from that agency."
P-045	Section II - Scope	The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBCs responsibility for environmental risk and references animal and plant health requirements in other contexts.	Explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. Explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.
P-046	Section II - Scope	The draft does not say how the Policy applies to research with existing IBC approvals. For example, some organisms have no risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.	Define a process for managing research with existing IBC approvals, including organisms without a BMBL risk group or containment recommendation for which the IBC has already assigned containment.
P-047	Section II - General definitions	Arthropod Containment Levels are not captured in the scope of this policy.	Revised the definition of laboratory research to include arthropod containment
P-048	Section II - General definitions	“Biomedical research” appears to be tied to whether the activity occurs at an NIH-funded institution rather than to the nature and purpose of the activity. Clinical research involving biohazards is also forced into a laboratory setting described by BSL or ABSL terminology.	Consider defining “biomedical research” by the nature and purpose of the activity, and address applicability to non-NIH-funded research at recipient institutions separately. Define clinical research involving biohazards independently of BSL/ABSL laboratory terminology.
P-049	Section III-A - Responsibilities of the Institution	Occupational health requirements lack clear triggers, assigned authorities, and	Include clear triggers, assigned authorities, and responsibility for developing and

ID	Section / item	Comment	Suggested change
		responsibility for developing and communicating required procedures.	communicating required occupational health procedures.
P-050	Section III-A - Responsibilities of the Institution	Retention and public-availability requirements differ by record type and award, and the draft does not map them.	Include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. For each, identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.
P-051	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The categories of NIH reportable incidents listed may have the "potential" to pose a significant risk to human health, but it is misleading to say they pose a significant risk to human health and could suggest to the public that these reported incidents are riskier than they actually are.	Replace the wording "that pose a significant risk to human health: with have the potential for significant risk to human health" in both the policy and on the incident report form.
P-052	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The wording of the BSL-3/ABSL-3 and BSL-4/ABSL-4 reporting requirement for "potential exposures" should be modified to align with the definition of "occupational exposure" in the select agent regulations for consistency and to eliminate any uncertainty related to potential exposure vs. occupational exposure requiring reporting.	Revise the "exposure" reporting requirement for BSL-3/ABSL-3 and BSL-4/ABSL-4 to read as follows: Any occupational exposure defined as any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to pathogens at BSL-3/ABSL-3/ACL-3 or BSL-4/ABSL-4 that may result from the performance of an employee's duties. Any exposure event that results in the activation of post-exposure medical treatment or surveillance protocols would be considered an occupational exposure. To simplify, the definition of "occupational exposure" could be added to the General Definitions section so that the statement here could be "Any occupational exposure."
P-053	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The wording of the BSL-3/ABSL-3 and BSL-4/ABSL-4 reporting requirement for releases should be modified to align with the definition of "release" in the select agent regulations for consistency and to eliminate any uncertainty related to "potential releases vs. releases that need to be reported.	Revise the BSL-3/ABSL-3 and BSL-4/ABSL-4 "release" reporting requirement to read as follows: Any release defined as any discharge of a BSL-3/ABSL-3/ACL-3 or BSL-4/ABSL-4 pathogen outside primary containment devices (e.g., biological safety cabinets, centrifuge safety cups, etc.) or secondary barriers (e.g., HEPA exhaust systems and other biocontainment facility boundaries). If the definition of "release" is moved to the General Definitions section, the policy can simply say "Any release" under the reporting section.
P-054	Section III-B - Responsibilities of the Institutional	The wording of BSL-2/ABSL-2 exposure reporting requirements should be aligned with the proposed definition of occupational exposure for BLS-3/ABSL-	Revise the BSL-2/ABSL-2 exposure reporting requirement to read as follows: Any incidents involving occupational exposures at BSL-2/ABSL-2/ACL-3 that require agent-specific

ID	Section / item	Comment	Suggested change
	Biosafety Committee (IBC)	3/ACL-3 and BSL-4/ABSL-4 exposure reporting.	post exposure medical treatment beyond basic first aid.
P-055	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The wording of the reporting exemption for minor spills of low-risk agents should be revised to clarify that the breach in containment is at the laboratory level and does not involve potential for community risk.	Revise the wording of the reporting exemption for minor spills of low-risk agents as follows: "Minor spills of low-risk agents, that do not involve a break of laboratory containment with potential for community risk, and that were properly cleaned and decontaminated, generally do not need to be reported."
P-056	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The wording of the incident report posting requirement should be revised to clarify that only NIH incident reports need to be posted on a public-facing webpage, not "all incident reports".	Revise the wording of the first sentence of the incident report posting requirement to read as follows: "Posting all NIH incident reports on a public-facing webpage on the website of the institution, using the incident reporting template."
P-057	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The 24 hour reporting requirement will be difficult to meet for any reportable incidents that occur on a Friday.	Replace the 24 hour reporting requirement with "(by the close of the next business day or as soon as the institution becomes aware of the incident)"
P-058	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The statement that minor spills of low-risk agents “generally do not need to be reported” does not specify whether this refers to reporting to NIH, the IBC, or both.	Clarify the applicable reporting level and distinguish between institutional/IBC reporting and external reporting to NIH.
P-059	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft allows recused members to count toward a quorum and does not specify the quorum or voting denominator, remote participation, or the use of ad hoc consultants. Some institutions will also have difficulty recruiting unaffiliated members.	A member recused because of a conflict should not count toward the quorum needed for action on that matter. Specify the quorum and voting denominator after recusal, expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.
P-060	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	Requirements for unaffiliated members and specialized expertise may be unworkable in small, rural, geographically isolated, or institution-dominated communities.	Expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Keep requirements for unaffiliated members and specialized expertise flexible while preserving meaningful independent input.
P-061	Section III-C - Responsibilities of the Principal Investigator (PI)	The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance.	Allocate responsibility for facilities and containment equipment among the institution, program leadership, facilities owner, BSO, PI, and equipment user.
P-062	Section III-D - Responsibilities of the National	How will the term "in a timely manner" be defined?	Define time range of the term "timely manner."

ID	Section / item	Comment	Suggested change
	Institutes of Health (NIH)		
P-063	Section IV-3 - Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members	Delegated review is a welcome modernization, but requiring every approval to be reported "in full" at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. The full committee's role after delegated approval is not defined.	Permit institutions to provide a concise approval log or aggregate report to the IBC, with records retained for audit. Define the full committee's role after delegated approval.
P-064	Section V-A - Requirements and Considerations for Risk Assessment of the Characteristics of the Biohazard	Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level.	Retain Risk Groups as a starting point and preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.
P-065	Section V-E - Risk Mitigation Strategies and Laboratory Containment	A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems.	Allow equivalent risk-based containment and provide technology-specific guidance.
P-066	Section V-E - Risk Mitigation Strategies and Laboratory Containment	The influenza language could apply to any construct containing any listed segment and does not specify what triggers BSL-3 enhanced containment.	Specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment.
P-067	Other Comments	Because of uncertainty in the final requirements, and given the expansion of institutional scope, review, documentation, public-posting, assurance, and reporting obligations, institutions cannot fully assess the burden or feasibility of the final policy.	Provide an opportunity for public review and comment on the next draft of the policy, and on the complete implementation materials, before the policy is finalized.

Draft incident reporting template (3)

ID	Section / item	Comment	Suggested change
I-003	Part 1. Institutional Information	"Incident reports should not include any personally identifiable identification of individuals involved in the incident (aside from the Principal Investigator's name)."	Remove reference to any names and other personal identifiable information
I-004	Other Comments	Is the National Biosafety Data and Safety Analysis Center (NBDSAC) subject to FOIA?	Clarify how confidentiality is going to be maintained in light of FOIA
I-005	Other Comments	Institutions have differing needs, and a single fixed template may not suit all of them.	Allow flexible templates to account for institutional needs.

Draft IBC meeting minutes template (3)

ID	Section / item	Comment	Suggested change
M-001	Other Comments	The meeting minutes template does not clearly distinguish among full IBC review, delegated review, and periodic/renewal review. If a notification/registration-only category is adopted, this should also be reflected in the template	Add separate or clearly identified categories for full IBC review, delegated review, and notification/registration-only activities, with documentation proportional to the level of oversight. Clarify that periodic/three-year reviews may use the same format as new registrations if they are conducted as de novo reviews.

Low priority comments (12)

Draft policy (8)

ID	Section / item	Comment	Suggested change
P-068	Section II - Scope	Extending the scope to include wild-type biological agents, as proposed, is a good idea.	—
P-069	Section II - General definitions	Inclusion of reassortment (especially with regard to influenza viruses) as form of genetic modification will be an improvement over current NIH Guidelines.	—
P-070	Section II General Definitions	The acronym GDMO is used throughout the body of the policy but never defined. Only Gene Drive is defined.	Add Gene Drive Modified Organism (GDMO) to the definitions sections and provide an appropriate definition to supplement the existing definitions provided for Gene Drive and Genetic modification.
P-071	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The responsibility described for the 6th bullet unnecessarily repeats part of the 5th bullet.	Revise the first sentence of the 6th bullet as follows: Petitioning NIH to lower the minimum containment for research involving RG3 and RG4 agents that have not previously been approved by NIH.
P-072	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The BSL-3/ABSL-3 and BSL-4/ABSL-4 reporting expectations for biological agents inventories should use terminology consistent with the select agent program for consistency to avoid uncertainty on what needs to be reported.	Replace the biological agent reporting wording as follows: Theft or loss of biological agents that may have public health consequences.
P-073	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The wording of the BSO's duties should be revised to clarify that the scope for conducting periodic inspections includes all BSL/ABSL/ACL research activities.	Revise the wording of the first bullet under BSO's duties as follows: "Conduct periodic inspections at all BSL/ABSL/ACL laboratories to ensure that laboratory biocontainment facilities and equipment are functioning properly, biosafety standards are rigorously followed, and IBC approval conditions for the conduct of research are being followed."
P-074	Section III-B - Responsibilities of the Institutional Biosafety Committee (IBC)	The draft's effort to identify specific categories for immediate notification and follow-up reporting is supported. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.	Retain the specific categories and examples for immediate notification and follow-up reporting.
P-075	Section IV - Categories of Oversight for Research Based on Risk	The subsection identification scheme for this section is inconsistent, using numbers instead of letters.	Use IV-A, IV-B, etc.

Draft incident reporting template (1)

ID	Section / item	Comment	Suggested change
I-006 Proposed priority†	Part 4. Root Cause Analysis and Corrective Actions	Separate Root Cause analysis and Corrective Actions	Part 4 and Part 5 (include plan to prevent re-occurrence)

Draft IBC meeting minutes template (3)

ID	Section / item	Comment	Suggested change
M-002 Proposed priority†	General Meeting Information	New Business, Incidents, Inspections, IBC Trainings - needs a break from the information noted above that is required for each new submission for review	Correct formatting
M-003 Proposed priority†	New IBC Registrations and Amendments for Review	Clarify "Readout of Any Projects Approved by Delegated Review Document all approvals granted by delegated review (may be attached to the minutes as a list).	—
M-004 Proposed priority†	Other Comments	The template doesn't have headers distinguishing the different sections, so the review blends into other business.	If the formatting must be followed exactly, include clearer section breaks.

264. Fred Hutch Cancer Center

I am responding: On behalf of an organization

Name: Susan Parazzoli

Name of Organization: Fred Hutch Cancer Center

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer and infectious disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Under Section II, Scope, list number 2. Cells, viruses, or organisms, other than plants, that have been genetically modified; does this include past modifications not made by the PI?
In other words, does "genetically modified" include cells, viruses, or organisms that were modified previously by another investigator, institution, manufacturer, or commercial supplier? If so, please clarify whether all subsequent research involving such materials remains subject to the Policy regardless of the age, provenance, or nature of the original modification. Please also clarify what information investigators are expected to obtain regarding historical modifications when complete provenance is unavailable.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Advocate for continued use of Risk Groups as the baseline for risk assessment, especially for those that are being genetically modified.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached for multiple comments.

6. Other feedback relevant to this resource: See attached.

Uploaded File: Fred-Hutch-Comments-to-NIH-Biosafety-Policy-10.19.26.docx

Policy Scope

1. Under Section II, Scope, list number 2. *Cells, viruses, or organisms, other than plants, that have been genetically modified*; does this include past modifications not made by the PI?

In other words, does "genetically modified" include cells, viruses, or organisms that were modified previously by another investigator, institution, manufacturer, or commercial supplier? If so, please clarify whether all subsequent research involving such materials remains subject to the Policy regardless of the age, provenance, or nature of the original modification. Please also clarify what information investigators are expected to obtain regarding historical modifications when complete provenance is unavailable.

Review pathways and low-risk research

2. Will NIH retain an exemption/no-IBC-review pathway for **low-risk activities** such as certain plasmids, PCR products, transgenic rodents, and genetically modified cells?

3. Please **define** "low-risk transgene," "well-characterized cell line," "minor amendment," and "transgenic organism" and please provide examples for delegated versus full-committee review.

4. Are **naked DNA/RNA**, non-expressing PCR products, oligonucleotides, and extracted nucleic acids outside cells, organisms, or viruses subject to the Policy? If so, under what category?

Clinical Research:

5. Please **confirm that clinical activities** conducted solely for diagnosis, treatment, or routine patient care—including standard blood draws, specimen transport, diagnostic testing, and disposal—are outside the Policy because they are not biomedical research. For collections serving both clinical care and research, please specify when IBC jurisdiction begins: at collection, upon separation or designation of the research aliquot, or when research-specific processing begins.

6. **Routine human specimens**: Does NIH intend all biomedical research handling unfixed human blood, tissues, bone marrow, primary cells, or other native human specimens to receive IBC review because such materials may contain adventitious agents, or only work presenting a defined risk above ordinary Bloodborne Pathogens/Universal Precautions controls?

7. **Adventitious-agent threshold**: When is a primary cell considered contaminated by an adventitious agent? Is the phrase a universal assumption for all primary cells, or does it require a known, suspected agent?

8. **CAR T-cell replication**: In the phrase "products that are capable of shedding, replicating, or integrating," does "replicating" mean autonomous replication of a biological agent/vector, or does it include normal mitotic proliferation of cellular products such as CAR T cells?

Incidents and noncompliance reporting

9. Please define “compliance violation,” “significant problem,” “incident,” “potential exposure,” “loss of containment,” “release,” “facility failure,” “equipment failure,” and “potential laboratory-acquired infection.” NIH should establish objective thresholds that distinguish events requiring internal institutional correction, events requiring IBC review, and events requiring NIH notification

10. Would the following be NIH-reportable absent an exposure or release: failure to wear a lab coat or use of incorrect PPE; late annual training; an expired BSC certification; incomplete signage; work by a person omitted from a protocol roster; or a minor deviation from an approved SOP?

11. Are all lower-risk incidents reviewed by the IBC required to generate individual public incident reports, including animal bites, scratches, escapes, first-aid-only events, and low-risk exposures?

12. May institutions report low-risk, non-NIH-reportable events in aggregate on an annual or semiannual basis to preserve transparency while avoiding a disproportionate administrative burden?

13. **Suggestion: NIH should not require Principal Investigator’s name to appear on publicly posted incident reports. This is not necessary to communicate the nature of the incident, root causes, institutional response or corrective actions. Naming the PI would only discourage reporting and undermine the function of our biosafety program because we rely on these reports to investigate individual events, identify trends, recommend mitigation measures and develop training that prevents future injuries, exposures, and releases. It also places an undue personal responsibility on the PI when the incident may involve institutional systems, facilities or equipment. NIH could collect PI names confidentially when needed, and only require posting of lessons learned, corrective actions, and prevention of recurrence. We would also like to remind the NIH at their own engagement process- feedback was given that anonymous reporting encouraged reporting**.

Meeting minutes and public posting

14. Please confirm that minutes may be approved at the next **regularly scheduled** convened meeting and posted immediately afterward; no interim or specially convened meeting is required solely to approve minutes. If meeting dates are prolonged, then specify a timeframe for posting the minutes. Most IBCs meet monthly or bi-monthly. NIH should clarify that institutions are not required to convene a special meeting solely to approve minutes

15. Is the draft template mandatory in layout and field order, or may institutions **use their own format** if it captures NIH-defined minimum content? Current NIH guidance specifically states that use of the specific template is not required.

16. Can **routine low-risk protocols and delegated approvals be presented in tables, appendices, or batched summaries** rather than full narrative entries for every protocol in the IBC minutes? Can the NIH adopt some sort of risk-appropriate documentation standard so that lower-risk work would require a less complex description? Current NIH minutes allow for variability in complexity and risk with documentation proportional to those levels

Implementation Period

17. Please allow at least 12 months for full implementation after final guidance and templates are provided so that institutions can keep up with the current workload and have time to identify newly covered work.

18. Request that the NIH submit another draft policy for review before finalizing. The current NIH Guidelines have been in existence for 50 years and rushing into a new Policy will leave unintended gaps and possible oversights with potentially serious consequences.

    If NIH makes substantial changes to scope, review requirements, incident-reporting thresholds, public-disclosure requirements, or institutional assurance requirements in response to these comments, NIH should provide an additional opportunity for stakeholder review before those provisions become effective.

265. Mr. M

I am responding: On behalf of myself

Name: Mr. M

Name of Organization: Southwest University

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As a CSHEMA affiliate, I support the following response letter to the proposed NIH Biosafety Policy for Research Involving Biohazards. See attached letter.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: CSHEMA_NIH_Comments-10-12-2026.pdf

Description: As a CSHEMA affiliate, I support the following response letter to the proposed NIH Biosafety Policy for Research Involving Biohazards. See attached letter.

Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards

Response to NOT-OD-26-112

October 12, 2026

Submitted Electronically

The Campus Safety, Health, and Environmental Management Association (CSHEMA) is the premier association for environmental health and safety leadership in higher education. CSHEMA represents institutions that range from large research-intensive universities with mature biosafety programs to smaller colleges that may have limited or no dedicated biosafety staff. Our members include biosafety professionals, environmental health and safety practitioners, and institutional leaders responsible for implementing biosafety requirements across diverse research and teaching environments.

CSHEMA appreciates NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions. **Due to such uncertainty in the final requirements, CSHEMA encourages NIH to provide an opportunity for public review and comment on the next draft before it is finalized.**

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." The policy should clarify whether precautionary post exposure prophylactic treatment is considered "agent-specific treatment". It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

6. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

CSHEMA recommends that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

Conclusion

CSHEMA supports NIH's goal of modernizing biosafety oversight and appreciates the draft's movement toward broader risk awareness, clearer incident thresholds, delegated review, and national safety learning. For the policy to succeed, however, modernization must strengthen the institutional systems that perform biosafety work rather than simply expand their obligations.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified

local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

CSHEMA respectfully requests that NIH revise the draft consistent with these recommendations, release complete implementation materials for public review, pilot key templates and processes, and provide a minimum 24-month phased implementation period. CSHEMA welcomes continued engagement and would be pleased to assist NIH in testing implementation resources or gathering additional institutional perspectives.

Sincerely,



Robin Izzo
President
Campus Safety, Health, and Environmental Management Association

266. University of Wisconsin-Milwaukee

I am responding: On behalf of an organization

Name: Jill McClary-Gutierrez

Name of Organization: University of Wisconsin-Milwaukee

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Expansion of scope beyond recombinant techniques is logical and appropriate
The scope of the new policy ("all biomedical research, in laboratory settings, involving biohazards") is an appropriate change from the previous NIH Guidelines. The new scope limits oversight to NIH's funding priorities by excluding plants, while increasing oversight to include wild-type pathogens. These changes are logical and aligned with the purpose of the Policy.

Definition of "biohazards" requires significant clarification and examples
The Policy defines research involving biohazards as "research involving known or potential risk to human health and any of the following:
1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above."
NIH should provide examples to clarify the phrase "known or potential risk to human health." This phrasing as provided is far too broad and open to interpretation. What level of risk would be considered significant, or is any risk, no matter how small, subject to the Policy's oversight? For example, wild-type Risk Group 1 agents are excluded from the Policy, presumably because of a lack of risk to human health; but it is unclear if a genetically modified Risk Group 1 agent expressing only a reporter transgene would be considered a biohazard under the Policy and who is meant to make that determination. The existing NIH Guidelines contain specific Exemptions where the agents in use do not present a significant risk to health or the environment (e.g., E. coli K-12, S. cerevisiae, certain activities involving transgenic rodents, etc). It is unclear if these organisms would be Exempt when genetically modified under the new Policy. Similarly, it is unclear if all primary cells and cell lines (including, for example, murine or insect cells) are included within the Policy scope, or only those that harbor human infectious agents.

Definition of "toxin" requires refinement
The Policy defines Toxin as "A protein or peptide produced by living organisms that causes harm in

humans." This definition is far too vague. First, not all biological toxins are proteins or peptides (e.g., T-2 toxin); are such toxins excluded from the policy's oversight? Second, describing a toxin as any protein that "causes harm in humans" includes other protein classes that are not toxins (e.g., oncogenic proteins, allergens). NIH should refine this definition and should include reference to a practical LD50, as the scientific standard for classifying toxicity.

Definitions of "emerging agent or organism" and "zoonotic" require clarification
The definitions of "emerging agent or organism" and "zoonotic" require significant clarification and examples to ensure they are reasonably applied, especially given the Policy's requirement for NIH review and input for any research involving an emerging or zoonotic agent without a current RG or containment level classification. As written, the definitions for these agent categories are extremely broad and would be difficult to apply in practice. For example, would studies that involve screening environmental samples for previously unidentified organisms or strains require NIH review for each strain identified? At what point in such research would NIH review be required: at the initiation of the work because there is a chance of identifying a new agent, or only after the agent has been fully characterized and deemed both novel and potentially pathogenic? What constitutes a "newly identified" agent? Must it be a species that has not been published in literature? What about new strains of previously known species? What qualifies as "reasonable suspicion" of transmission from animals to humans? Such questions about practical application of the definitions limit their utility and may lead to overwhelming need for NIH input on relatively low risk (BSL-2) studies. We suggest that NIH limit the definitions to organisms with potential for serious or lethal human disease, as assessed by the PI in consultation with the IBC. We also request clarification regarding expected oversight for studies involving screening or culture of unknown organisms from clinical or environmental samples.

Clarify "biomedical research" definition and supply a definition of "research"
The Policy's definition of "biomedical research" under its scope is written as "research on a topic that is within the mission of the NIH, including applicability to: research supported by NIH, and non-NIH funded research that is conducted at an institution that receives any NIH funding." NIH should update the definition to address the following gaps.
First, NIH should clarify what is meant by "non-NIH funded research". As written, it is unclear if this refers to any research that is not funded by the NIH, or any funded research that is not funded by the NIH.
Second, NIH should take this new Policy implementation as an opportunity to clarify a definition of "research." Biohazards are used in many different non-research projects, such as teaching, clinical testing, or manufacturing. While safety is necessary for all biohazard handling, the oversight structures of this Policy are specific to research and should be clarified as such with a definition of research. As a model, human subjects research requiring Institutional Review Board (IRB) review has clear and established definitions of both "human subjects" and of "research".

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Creation of delegated review category is a positive change
The new Policy creates a pathway for "delegated" review by an individual or subgroup of IBC members which does not exist in the current NIH Guidelines. This review pathway is a positive change, allowing for faster turnaround for low-risk studies and creating processes that are akin to other compliance committees (e.g., IRB, IACUC).

Refining definitions is necessary to ensure oversight is calibrated to risk
As stated previously, NIH must refine and provide examples for terms including “biohazards”, “emerging agents”, and “zoonotic” to ensure it is clear what level of human health risk is truly relevant to the new Policy. This clarification should help to ensure that the tiered oversight structure in the new Policy is properly calibrated to risk. Additional terminology that is unclear or appears to require excessive review is listed below. NIH should provide examples of what falls within these terms and what does not for consistent application of the Policy:
- “Primary cells that may be contaminated with adventitious agents”: By definition, primary cells are less well-characterized than other cell lines. Primary cells collected from laboratory rodents that have not been treated with infectious agents should not require full IBC review.
- “Transgenic organisms”: Clarify the difference between “genetically modified” and “transgenic” for oversight purposes.
- “Reporter or low-risk transgenes”: Provide examples for consistent implementation.
- “Well-characterized cell lines”: What qualifies as “well-characterized”?

3. Continued utility of Risk Groups: Risk Group lists must be frequently updated and publicly shared by NIH
Reliance on Risk Groups as a baseline for risk assessment is acceptable, as this practice is already widespread and allows a base level of consistency between institutions. However, because the Policy continues to depend on Risk Groups and requires NIH input for Risk Group determination, the NIH must publicly share and frequently update Risk Group lists based on requests for input from institutions. This practice of sharing all Risk Group determinations publicly at the federal level will promote consistency across institutions, while reducing administrative burden at both institutional and federal levels for review of identical agents from multiple institutions.

Clarify the role of the BMBL as an advisory document
The existing NIH Guidelines contain requirements for various biosafety levels, which the new Policy removes in favor of aligning biosafety levels with those described in Biosafety in Microbiological and Biomedical Laboratories (BMBL). We support this change as it helps to reduce redundancy and/or conflict between biosafety level definitions applied by different agencies. However, we believe the new Policy should clarify its expectation in use of the BMBL as an advisory document. The BMBL was not written as a policy requirement. While it provides an excellent framework for best practice, institutions should be able to adapt and deviate from the BMBL when justified and appropriate for their specific circumstances.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public posting of individual incident reports will create privacy issues, increase administrative burden, and reduce reporting rates.
We have significant concern regarding the requirement for public posting of individual incident reports, especially given the level of detail included in the required Incident Reporting template and the minimal immediate value in public reporting on low-risk incidents. While we agree with the aim of transparency and the value of consistency in reported data across institutions, we do not see these values truly enhanced by public reporting of individual incidents on institutional websites for the following reasons:

- The Policy includes development of a National Biosafety Data and Safety Analysis Center where all NIH-reportable and voluntarily submitted incident reports would be aggregated, de-identified, and analyzed. This Center provides true value in advancing the metascience of biosafety by centralizing incident data. Institutionally posted incident reports do not add to that goal.
- Short summaries of incidents are already included for required public posting in IBC Meeting Minutes according to the required template. If the goal of posting individual incident reports is to ensure public awareness, posting of IBC Meeting Minutes already meets this need, making posting of individual Incident Reports redundant.
- Regardless of the ability to redact names from incident reports, we are concerned that posting of individual incident reports will violate privacy of those involved. At smaller institutions or in smaller research labs, listing an individual's job title effectively identifies that individual. We have significant concern about the implications of this for protecting individual health information.
- Instead of providing value, we strongly suspect that researchers may view incident report posting as punitive and that this requirement will significantly decrease the number of incident reports notified to biosafety programs, thus directly reducing biosafety programs' ability to promote the safety that the Policy aims to support.

We instead suggest an alternative approach to strike a balance between immediate transparency, institutional administrative burden, and advancement of biosafety:

- If the goal of incident report posting is to improve biosafety and increase public transparency, we believe the required reporting structure for NIH-reportable incidents and collection of data in the National Biosafety Data and Safety Analysis Center, without institutional posting of individual reports, meets this need for NIH-reportable incidents.
- Non-NIH-reportable incidents are lower risk, thus making immediate posting for public transparency of limited value and a potentially high administrative burden. We propose that institutions instead be required to post or provide to NIH an annual summary of these lower risk incidents at their institutions. This would be similar to annual reporting of OSHA recordable incidents. This process would remove the privacy concerns around posting individual reports, while maintaining a focus on transparency and accountability to the public and encouraging institutions to periodically evaluate their incident data for trends, thus promoting continuous improvement.

24-hour notification for compliance violations is not reasonable or valuable

The new Policy codifies immediate (i.e., within 24 hours) notification for certain types of incidents, which has been the expected practice under the existing NIH Guidelines for high-risk incidents. However, the new Policy stipulates required immediate notification for all NIH-reportable incidents, including "any compliance violations at any BSL/ABSL". Compliance violations that do not also involve a serious incident should require the standard 30-day reporting only. This reduces the administrative burden on reporting these cases when there is no immediate risk resulting from the violation, while maintaining a standard of reporting all compliance violations to the NIH.

Incident Reporting Template should not require funding information

The Incident Reporting Template includes fields for NIH grant number, NIH funding institute, and NIH program officer. We do not see the value in including this information in incident reports and suspect it will be perceived as punitive, leading to fewer incident reports and undermining the safety culture that the Policy aims to support.

IBC Meeting Minutes Template should be recommended, not required
Requiring a specific IBC Meeting Minutes template creates an administrative burden and compliance challenge that does not directly support safety or transparency. While we can see value in a shared format across institutions, this value does not outweigh the administrative burden of updating existing, functional systems to match a specific template. We suggest instead that the Meeting Minutes Template be provided as a recommended resource, as was done in 2025 when the requirement for public posting of meeting minutes went into effect. To support the recommended template, there should also be a clear list of the minimum required information to help institutions meet compliance requirements. No other similar compliance committee (e.g., IRB, IACUC) has a required meeting minutes template at the federal level.

6. Other feedback relevant to this resource: Implementation timeline is too short
The 6-month implementation timeline is far too short. The Policy significantly expands scope from the prior NIH Guidelines, and effective implementation will require institution-wide policy changes, development of new procedures and forms to match required templates, and re-education of campus stakeholders. As a public academic institution, many of our campus processes are influenced by fiscal or academic year calendars, making a timeline of less than one year impractical. We request at least one year, as has been typical for other new federal biosafety policies in recent years.

Supporting materials should be provided for Biosafety Assurance documentation
NIH should supply an example of the Biosafety Assurance documentation to aid institutions in meeting this new requirement. This resource would be akin to the Assurance Sample Document provided by OLAW for verifying compliance with the Policy on Humane Care and Use of Laboratory Animals.

Uploaded File: FENIH-Biosafety-Policy-for-Research-Involving-Biohazards_Comments-from-UWM-IBC.pdf

Description: Comments from UW-Milwaukee and UW-Milwaukee Institutional Biosafety Committee

UNIVERSITY OF WISCONSIN MILWAUKEE | Division of Research

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To: National Institutes of Health Office of Science Policy

From: The Office of the Vice Chancellor for Research and the Institutional Biosafety Committee (IBC), University of Wisconsin-Milwaukee

RE: Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

October 15, 2026

The University of Wisconsin-Milwaukee thanks the NIH for providing an opportunity to comment on the draft NIH Biosafety Policy for Research Involving Biohazards. We are writing on behalf of the University to provide our feedback.

Overall, we agree with the risk-based and technology-agnostic approach to biosafety taken by the draft NIH Policy. This approach is a welcome change from the existing NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

However, we have significant concerns about implementation of the draft NIH Policy as written. These concerns focus primarily on unclear scope, vague definitions, and increased administrative burden for our Biosafety Program and PIs. Specific comments are provided below based on the NIH's requested feedback categories.

Comments regarding appropriateness of scope and definitions

Expansion of scope beyond recombinant techniques is logical and appropriate

The scope of the new policy ("all biomedical research, in laboratory settings, involving biohazards") is an appropriate change from the previous NIH Guidelines. The new scope limits oversight to NIH's funding priorities by excluding plants, while increasing oversight to include wild-type pathogens. These changes are logical and aligned with the purpose of the Policy.

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NIH should provide examples to clarify the phrase "known or potential risk to human health." This phrasing as provided is far too broad and open to interpretation. What level of risk would be considered significant, or is any risk, no matter how small, subject to the Policy's oversight? For example, wild-type Risk Group 1 agents are excluded from the Policy, presumably because of a lack of risk to human health; but it is unclear if a genetically modified Risk Group 1 agent expressing only a reporter transgene would be considered a biohazard under the Policy and who is meant to make that determination. The existing NIH Guidelines contain specific Exemptions where the agents in use do not present a significant risk to health or the environment (e.g., *E. coli* K-12, *S. cerevisiae*, certain activities involving transgenic rodents, etc). It is unclear if these organisms would be Exempt when genetically modified under the new Policy. Similarly, it is unclear if all primary cells and cell lines (including, for example, murine or insect cells) are included within the Policy scope, or only those that harbor human infectious agents.

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Comments regarding appropriateness of tiered oversight and calibration to risk

Creation of delegated review category is a positive change

The new Policy creates a pathway for "delegated" review by an individual or subgroup of IBC members which does not exist in the current NIH Guidelines. This review pathway is a positive change, allowing for faster turnaround for low-risk studies and creating processes that are akin to other compliance committees (e.g., IRB, IACUC).

Refining definitions is necessary to ensure oversight is calibrated to risk

As stated previously, NIH must refine and provide examples for terms including "biohazards", "emerging agents", and "zoonotic" to ensure it is clear what level of human health risk is truly relevant to the new Policy. This clarification should help to ensure that the tiered oversight structure in the new Policy is properly calibrated to risk. Additional terminology that is unclear or appears to require excessive review is listed below. NIH should provide examples of what falls within these terms *and* what does not for consistent application of the Policy:

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- "Reporter or low-risk transgenes": Provide examples for consistent implementation.
- "Well-characterized cell lines": What qualifies as "well-characterized"?

Comments regarding continued utility of Risk Groups (RGs) as a baseline for risk assessment versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Risk Group lists must be frequently updated and publicly shared by NIH

Reliance on Risk Groups as a baseline for risk assessment is acceptable, as this practice is already widespread and allows a base level of consistency between institutions. However, because the Policy continues to depend on Risk Groups and requires NIH input for Risk Group determination, the NIH must publicly share and frequently update Risk Group lists based on requests for input from institutions. This practice of sharing all Risk Group determinations publicly at the federal level will promote consistency across institutions, while reducing administrative burden at both institutional and federal levels for review of identical agents from multiple institutions.

Clarify the role of the BMBL as an advisory document

The existing NIH Guidelines contain requirements for various biosafety levels, which the new Policy removes in favor of aligning biosafety levels with those described in Biosafety in Microbiological and Biomedical Laboratories (BMBL). We support this change as it helps to reduce redundancy and/or conflict between biosafety level definitions applied by different agencies. However, we believe the new Policy should clarify its expectation in use of the BMBL as an advisory document. The BMBL was not written as a policy requirement. While it provides an excellent framework for best practice, institutions should be able to adapt and deviate from the BMBL when justified and appropriate for their specific circumstances.

Comments regarding mechanisms to encourage and accommodate voluntary compliance

No comments

Comments on incident reporting and meeting minutes, including templates

Public posting of individual incident reports will create privacy issues, increase administrative burden, and reduce reporting rates.

We have significant concern regarding the requirement for public posting of individual incident reports, especially given the level of detail included in the required Incident Reporting template and the minimal immediate value in public reporting on low-risk incidents. While we agree with the aim of transparency and the value of consistency in reported data across institutions, we do not see these values truly enhanced by public reporting of individual incidents on institutional websites for the following reasons:

- The Policy includes development of a National Biosafety Data and Safety Analysis Center where all NIH-reportable and voluntarily submitted incident reports would be aggregated, de-identified, and analyzed. This Center provides true value in advancing the metascience of biosafety by centralizing incident data. Institutionally posted incident reports do not add to that goal.
- Short summaries of incidents are already included for required public posting in IBC Meeting Minutes according to the required template. If the goal of posting individual incident reports is to ensure public awareness, posting of IBC Meeting Minutes already meets this need, making posting of individual Incident Reports redundant.
- Regardless of the ability to redact names from incident reports, we are concerned that posting of individual incident reports will violate privacy of those involved. At smaller institutions or in smaller research labs, listing an individual's job title effectively identifies that individual. We have significant concern about the implications of this for protecting individual health information.
- Instead of providing value, we strongly suspect that researchers may view incident report posting as punitive and that this requirement will significantly decrease the number of incident reports notified to biosafety programs, thus directly reducing biosafety programs' ability to promote the safety that the Policy aims to support.

We instead suggest an alternative approach to strike a balance between immediate transparency, institutional administrative burden, and advancement of biosafety:

- If the goal of incident report posting is to improve biosafety and increase public transparency, we believe the required reporting structure for NIH-reportable incidents and collection of data in the

National Biosafety Data and Safety Analysis Center, without institutional posting of individual reports, meets this need for NIH-reportable incidents.

- Non-NIH-reportable incidents are lower risk, thus making immediate posting for public transparency of limited value and a potentially high administrative burden. We propose that institutions instead be required to post or provide to NIH an annual summary of these lower risk incidents at their institutions. This would be similar to annual reporting of OSHA recordable incidents. This process would remove the privacy concerns around posting individual reports, while maintaining a focus on transparency and accountability to the public and encouraging institutions to periodically evaluate their incident data for trends, thus promoting continuous improvement.

24-hour notification for compliance violations is not reasonable or valuable

The new Policy codifies immediate (i.e., within 24 hours) notification for certain types of incidents, which has been the expected practice under the existing NIH Guidelines for high-risk incidents. However, the new Policy stipulates required immediate notification for *all* NIH-reportable incidents, including "any compliance violations at any BSL/ABSL". Compliance violations that do not also involve a serious incident should require the standard 30-day reporting only. This reduces the administrative burden on reporting these cases when there is no immediate risk resulting from the violation, while maintaining a standard of reporting all compliance violations to the NIH.

Incident Reporting Template should not require funding information

The Incident Reporting Template includes fields for NIH grant number, NIH funding institute, and NIH program officer. We do not see the value in including this information in incident reports and suspect it will be perceived as punitive, leading to fewer incident reports and undermining the safety culture that the Policy aims to support.

IBC Meeting Minutes Template should be recommended, not required

Requiring a specific IBC Meeting Minutes template creates an administrative burden and compliance challenge that does not directly support safety or transparency. While we can see value in a shared format across institutions, this value does not outweigh the administrative burden of updating existing, functional systems to match a specific template. We suggest instead that the Meeting Minutes Template be provided as a recommended resource, as was done in 2025 when the requirement for public posting of meeting minutes went into effect. To support the recommended template, there should also be a clear list of the minimum required information to help institutions meet compliance requirements. No other similar compliance committee (e.g., IRB, IACUC) has a required meeting minutes template at the federal level.

Comments on implementation, resources, and guidance

Implementation timeline is too short

The 6-month implementation timeline is far too short. The Policy significantly expands scope from the prior NIH Guidelines, and effective implementation will require institution-wide policy changes, development of new procedures and forms to match required templates, and re-education of campus stakeholders. As a public academic institution, many of our campus processes are influenced by fiscal or

academic year calendars, making a timeline of less than one year impractical. We request at least one year, as has been typical for other new federal biosafety policies in recent years.

Supporting materials should be provided for Biosafety Assurance documentation

NIH should supply an example of the Biosafety Assurance documentation to aid institutions in meeting this new requirement. This resource would be akin to the Assurance Sample Document provided by OLAW for verifying compliance with the Policy on Humane Care and Use of Laboratory Animals.

Other Comments

NIH should be held to a specific timeline for reviewing containment lowering requests and determining containment levels

The Policy indicates that NIH is responsible for "determining the appropriate containment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available" and "reviewing requests for lowering containment levels in a timely manner." These activities, which have direct impact on the ability of researchers to begin work, should be held to a reasonable and specific timeline. The policy assigns specific timeline requirements for IBCs related to incident reporting (24 hours or 30 days); NIH should hold themselves to a similar standard as a demonstration of shared responsibility and commitment to enabling safe and secure biomedical research. "A timely manner" is not specific enough.

UW-Milwaukee is committed to protecting the health and safety of our personnel and community. We ask NIH to make changes to and provide clarifications for the draft Policy as described above. We believe these changes and clarifications will allow for the Policy's effective implementation in a manner that promotes safety, allows flexibility, and reduces unnecessary administrative burden.

Sincerely,

[redacted]

Ali Abedi, PhD
Vice Chancellor for Research

Jill McClary-Gutierrez, PhD, RBP(ABSA)
Biological Safety Officer

[redacted]

Brad De Pons, MLS(ASCP)
IBC Chair

267. Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center

I am responding: On behalf of an organization

Name: Elizabeth Burrola

Name of Organization: Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: see attached document

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): see attached document

3. Continued utility of Risk Groups: see attached document

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): see attached document

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: see attached document

6. Other feedback relevant to this resource: see attached document

Uploaded File: Recommendations-to-OSP-RE-Draft-Policy-10-16-2026.docx

We support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate

director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety

program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and

near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request.

Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

Policy source

Draft NIH Biosafety Policy for Research Involving Biohazards, NIH Notice NOT-OD-26-112, released August 19, 2026. Section references throughout refer to this draft.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

268. COGR, AAU, & APLU

I am responding: On behalf of an organization

Name: Kristin West

Name of Organization: COGR, AAU, & APLU

Type of Organization: Other

Type of Organization - Other: Non-profit associations of academic research institutions

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Not applicable

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attached comment letter.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see attached comment letter.

3. Continued utility of Risk Groups: Please see attached comment letter.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see attached comment letter.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attached comment letter.

6. Other feedback relevant to this resource: Please see attached comment letter.

Uploaded File: AAU-APLU-COGR-final-response-to-NIH-Biosafety-Policy-Oct-2026.pdf

Description: Joint Letter from AAU, APLU, and COGR regarding Draft NIH Biosafety Policy for Research Involving Biohazards

October 16, 2026

Via Email to: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/.

National Institutes of Health
Office of Science Policy
Attn: Cari Young, Sc.M., Director of Biosafety, Biosecurity, and Emerging Bioteechology Policy Division

RE: Response to Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards

To Whom It May Concern:

The Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and COGR write to offer comments in response to the Draft NIH Biosafety Policy for Research Involving Biohazards (Draft Policy) published in the Federal Register on September 14, 2026. [91 FR 58132].

Founded in 1900, AAU comprises 69 of America's leading research universities that transform lives through education, research, and innovation. Research universities, including AAU members, have a long-standing partnership with the federal government to advance science and technology in the national interest. This partnership, rooted in World War II, has been central to U.S. global leadership in science and technology.

APLU is a membership organization that advances the mission of land-grant and public research universities. Founded in 1887, APLU is the oldest higher education association in the United States. Its U.S. membership consists of more than 240 land-grant and public research universities, state university systems, and affiliated organizations spanning across all 50 states, the District of Columbia, and five U.S. territories. The association and its members

collectively focus on increasing student success and workforce readiness; promoting pathbreaking scientific research; and bolstering economic and community engagement. Annually, its U.S. member campuses enroll 4.6 million undergraduates and 1.4 million graduate students, award 1.3 million degrees, employ 1.3 million faculty and staff, and conduct $70 billion in university-based research.

COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for over 230 research universities and affiliated academic medical centers and research institutes. Our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge. We advocate for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.

The academic research institutions that AAU, APLU, and COGR represent understand and support NIH's desire to update its current Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines") beyond the changes that were incorporated into those Guidelines in April 2024. Our member institutions are leaders in the conduct of biomedical research and fully support risk-based policies that protect researchers and the public from biohazards, while facilitating conduct of the broad spectrum of life sciences research necessary to ensure America's ability to understand and address threats to individual and public health. They also support regulations that embue biosafety officers (BSOs) and institutional biosafety committees (IBCs) with the power and authority to provide oversight for research involving biohazards.

Unfortunately, the Draft Policy does not callibrate required controls to actual risk presented, particularly in the case of lower-risk research activities. During the stakeholder consultation process, we were encouraged by discussions regarding how the Draft Policy could take a more risk-based approach to regulation. However, the Draft Policy does not retain many of the risk-based features of the NIH Guidelines. Instead, it adopts an overly risk-averse approach that substantially increases institutions' review and oversight responsibilities for low-risk research that was previously exempt.

The Draft Policy also places significant responsibilities on biosafety officers (BSOs), Institutional Biosafety Committees (IBCs), and institutions, but it fails

to empower them to carry out these responsiblities with sufficient independence and authority, along the lines that institutional review boards (IRBs) and institutional animal care and use committees (IACUCs) do under their governing regulations. Instead, the Draft Policy's vast scope (which includes virtually ALL research involving biological agents conducted at any institution that receives NIH funding), coupled with its overly prescriptive and risk averse requirements for IBC review, oversight and reporting functions, will substantially increase administrative burden while diverting limited biosafety resources from higher-risk activities, potentially undermining, rather than increasing, laboratory and public safety. Further, despite requiring institutions to provide review and oversight for non-NIH/non-federally funded research, the Draft Policy provides neither statutory support for these requirements nor mechanisms to reimburse institutions for associated implementation costs. Accordingly, as an overarching comment, we urge NIH to reevaluate both the scope of the Draft Policy and its risk calibration.

Below, are additional general comments regarding the Draft Policy, followed by comments and recommendations on specific policy provisions. In addition, our organizations recommend NIH consider using a notice of proposed rulemaking that includes the statutory basis for the proposed changes and a regulatory-impact analysis to facilitate such an extensive policy change.

GENERAL COMMENTS

▪**Intersection between Draft Policy and United States Government Policy for Stopping High Risk Life Sciences Research ("USG Policy"):** Given the Draft Policy's coverage of "research involving biohazards" and the USG Policy's coverage of broadly defined "Potential Dangerous Gain of Function (DGOF) Research" and "Other Risky International Research," there is substantial potential for overlap between the two policies. Unfortunately, the USG Policy had not been issued at the time that NIH was collecting stakeholder input on the Draft Policy. Further, NIH has not yet issued its implementation guidance for the USG Policy. Thus, institutions do not have any information on how NIH anticipates the Draft Policy will intersect with the USG Policy. Accordingly, it seems premature to collect stakeholder input on the Draft Policy, until NIH is in a position to provide these details.
Recommendation: Our associations urge NIH to extend the final date of the comment period on the Draft Policy to a date that falls at least 60 days after NIH has released its implementation guidance for the USG Policy and provides information on how the two policies intersect.

▪**Scope of Draft Policy Exceeds Statutory Authority:** NIH cites no statutory authority to support extending the scope of the Draft Policy to "non-funded NIH research that is conducted . . . at an institution that receives any NIH funding" ("Funded Institution"). Indeed, the only reference to biological agents and toxins contained in the statute prescribing the NIH director's duties/authorities is a requirement for the director to consult with named federal agencies/offices, "as appropriate, ***regarding research needs*** to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agents that may cause a public health emergency or other research needs related to emerging public health threats." [42 USC §282(b)(26) (***emphasis added***)].
Recommendation: NIH should provide the explicit statutory authority that authorizes it to include within the Draft Policy's scope non-federally funded research conducted at a Funded Institution, or, in the absence of such explicit authority, confine the Draft Policy's scope to NIH-funded research. Further, as noted, given the scope and magnitude of the Draft Policy, NIH should consider issuing the Draft Policy through the federal notice and comment rulemaking process, as opposed to issuing it as an agency policy.

▪**Draft Policy is Not Accurately Risk Calibrated and Places Substantial and Unjustified Administrative and Cost Burdens on Institutions:** Although the Draft Policy claims to support a risk-based approach to the review and oversight of biomedical research, its approach is not accurately risk calibrated. Specifically, the Draft Policy is overly risk-averse because it vastly increases the scope of research requiring IBC and/or NIH review by eliminating categories of low-risk research that were previously exempt from IBC review processes. Further, the Draft Policy's provisions concerning inspections, continuing reviews, and other oversight activities also lack risk calibration and/or are duplicative of oversight efforts in place via other regulatory and institutional mechanisms (e.g., IACUC semi-annual inspections, institutional lab safety inspections).

NIH's failure to "right-size" the draft Policy to the level of risk presented by specific activities results in unnecessary oversight for lower-risk activities, which in turn diverts resources that could be more effectively devoted to managing higher risk research. Further, NIH expects Funded Institutions to perform these responsibilites for ALL non-NIH funded research within the policy's scope. Yet, the policy contains no mechanism to ensure that institutions are fully reimbursed for costs associated with providing these

oversight functions. The Draft Policy also fails to adequately account for the security, privacy, and confidentiality risks created by the mandated public posting of information regarding biosafety procedures, IBC meeting minutes, the conduct of BSL/ABSL-3 or BSL/ABSL-4 research, and incident reports.

Recommendation:

(a) Develop and include within the Draft Policy categories of lower-risk research activities that do not require IBC and/or NIH review.

(b) As previously noted, remove non-NIH funded activities from the Draft Policy's scope. Alternatively, if NIH can demonstate appropriate statutory authority to support its regulation of these actitivies, it should specify within the Draft Policy how institutions will be compensated via NIH funding mechanisms for providing the oversight functions NIH is mandating.

(c) Modify the Draft Policy to permit IBCs to calibrate the type and frequency of oversight activities to actual risks presented by research activities and to coordinate with and prevent duplication of other inspection/review efforts carried out within the institution.

(d) Develop and include with the Draft Policy more detailed research security and privacy factors that institutions can rely upon to support the redaction of confidential and/or senstive private information from minutes and incident reports prior to posting, or alternatively, require only anonymized aggregated reporting.

▪**Draft Policy Uses BMBL in More than an Advisory Capacity:** The foreword to the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) explicitly states that it is an "advisory document," and it is not intended to be a "regulatory document." Rather, the BMBL was intended to be a periodically updated guidance document designed to support expert risk assessment and preserve institutional discretion. Despite this caution, the Draft Policy uses the containment levels set forth in the BMBL in a regulatory manner and constricts the IBC's ability to lower containment levels without NIH approval. The fact that the current issue of the BMBL was last revised prior to the COVID pandemic reveals a major flaw in using the BMBL in such a regulatory manner, i.e., the information in the BMBL is not continuously updated to reflect the latest scientific developments.

Recommendation: NIH should clearly state in the Draft Policy that the BMBL remains an advisory document, and as such, the establishment of containment levels by IBCs and NIH will be governed by current scientific evidence and may be higher *or lower* than BMBL-suggested levels when scientifically justified. Our organizations also urge NIH to ensure that there are adequate funding and operational mechanisms in place to continuously

update the BMBL to make certain that the information it contains accurately reflects the current state of scientific knowledge.

▪**Implementation Timeline is Too Short:** The Draft Policy specifies that it will take effect six months from the date of publication of the final policy with respect to new and existing NIH-funded research and non-NIH funded research conducted at an institution that receives NIH funding. The substantial increase in the portfolio of research that must be reviewed under the Draft Policy will place tremendous strain on institutions' existing IBC and biosafety operations and more than six months will be needed to take stock of new categories of research that require review; update institutional policies, processes, procedures, workflows, and associated tools; and train researchers and staff on the new policies/procedures.
Recommendation: Our organizations urge NIH to extend the effective date to 24 months from the date on which the final policy is published to afford institutions adequate implementation time. At a minimum, NIH should extend the effective date by at least 12 months from the final policy's publication date.

▪**Draft Policy is Unclear as to How Genetically Modified Plants will be Addressed:** Unlike the current policy, the Draft Policy does not include genetically modified plants within its framework, elminating a long-standing source of containment guidance for institutions, as well as best practices for greenhouse research, growth chamber research, pollen containment, reproductive isolation, and prevention of environmental release.
Recommendation: NIH should clarify how the government plans to handle guidance regarding genetically modified plants, including whether, NIH or another federal agency, plans on issuing guidance on this topic.

▪**Policy Format is Difficult to Follow:** The Draft Policy's lack of sequentially numbered sections and subsections make it difficult to use and cite.
Recommendation: To improve user friendliness, NIH should sequentially number each section and subsection of the Draft Policy.

SPECIFIC COMMENTS

Section I, Purpose: No comments.

Section II, Scope: See comments below.

▪**Draft Policy's Scope Is Overly Broad and Not Risk-Based:** The Draft Policy applies to "reseach involving known or potential risk to human health" and any of the items listed in provisions 1-4 of the Scope Section, including "[c]ells or organisms, other than plants," containing any of the items listed in items 1-3 of the Scope Section. However, virtually all organisms/cells contain some level of microorganismal contaminination. Further, there is no universal screening process for human pathogens, and some bacteria/microorganisms pose risk to only limited segments of the population (e.g., immunocrompomised individuals). Thus, as written, the Draft Policy **essentially treats every biological agent as a biohazard**, and by doing so it applies **to virtually any organism, with the exception of plants, without regard to actual risks presented. This approach serves to divert institutional/IBC time and resources to the assessment and review of lower-risk biomedical research and unnecessarily impedes the conduct of such research.**
Recommendation: To truly make the Draft Policy risk-based, we urge NIH to limit its scope to cells or organisms, other than plants, that contain one of the items in provisions 1-3, and that are known, or likely to cause, disease in humans. For example, certain toxins and self-aggregating proteins may not pose risk to human health in the absence of LD50 thresholds and/or clear evidence of causation of disease/harm. We also urge NIH to establish categories of lower-risk research such as research conducted at BSL-1/ABSL-1 that are excluded from the scope of the policy and/or are exempt from IBC or NIH review.

▪**Items within the Scope Section that Require Clarification:** The following provisions within the scope section are confusing and would benefit from additional clarification:

- **Laboratory Settings:** The term "laboratory settings" should be defined and distinguished from the defined term "laboratory research." Specifically, the Scope section states that the Draft Policy covers "all biomedical research, in ***laboratory settings,*** involving biohazards," [***emphasis added***] but the terms "laboratory settings" and "biohazards" are not defined. Instead, the Draft Policy defines the term :"Laboratory Research" as research conducted in BSL/ABSL 1-4 containment facilities. Accordingly, the scope of the policy is unclear. For example, are arthropod containment facilities, insectaries, or greenhouses considered to be "laboratory settings"? Does the Draft Policy apply to field research?
- **Clinical Research:** It is also unclear how the Draft Policy applies to clinical research, which is traditionally subject to other oversight mechanisms (e.g., OSHA bloodborne pathogen standard, hospital

infection control committee requirements). As previously noted, the policy defines Laboratory Research in terms of research conducted at BSL/ABSL levels in containment facilities but goes on to note that clinical research does not utilize traditional biosafety levels. Indeed, the only guidance the Draft Policy provides regarding risk assessment/mitigation in clinical settings is that "precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection."

Recommendation: NIH should clarify when and how the Draft Policy applies to research conducted in clinical settings. Additionally, our organizations recommend that risk assessment/mitigation in clinical setting utilize universal precautions as a baseline, coupled with additional controls (e.g., transmission precautions) based on hazard characteristics and routes of transmission associated with the items being studied. Along these same lines, NIH should clarify IBC review requirements for clinical research under Section IV.2, and detail how they intersect with other requirements in clinical settings (e.g., OSHA bloodborne pathogen requirements, hospital infectious control requirements, etc.).

- ***In Silico* Research:** The Draft Policy is unclear as to whether *in silico* research on items listed under provisions 1-4 of the Scope Section falls under the policy's auspices.

Recommendation: NIH should clarify whether *in silico* research on items listed under provisions 1-4 of the Scope Section does/does not fall within the scope of the Draft Policy, because such research does not necessarily involve a known or potential risk to human health.

- **Applicabilty to Lower-Risk Research Activities:** The draft policy is limited to "research involving known or potential risk to human health." This limitation suggests that the Draft Policy should not apply to certain lower-risk reseach (e.g., RG1 recombinant materials, gene drive modified organisms (GDMOs), and transgeneic animals at BSL-1/ABSL-1). However, several sections of the Draft Policy appear to require institutional registration and review of these lower-risk research activities without sufficient explanation and support for such risk calibration.

Recommendation: Given that NIH intends for the Draft Policy to be risk-based, NIH should specify those categories of lower-risk research activities that are excluded from the policy's scope. If all biomedical research involving the use of biological agents is included within the

Draft Policy's scope, then institutions will be required to devote a huge amount of time and resources to reviewing and providing oversight for low-risk research activities, in exchange for limited benefit in terms of improved safety.

°Examples of Activites Included/Excluded from the DRAFT POLICY: The Draft Policy does not include examples of research that do/do not fall within the policy's scope.
Recommendation: It would be very helpful to institutions if NIH provided concrete examples of research that is (a) within the Draft Policy's scope; and (b) excluded from the Draft Policy's scope. It would also be helpful to institutions if NIH clarified whether/how the Draft Policy applies to animal pathogens and other zoonotic risks, agricultural pathogens, plant pathogens, phages, environmental organisms, prions, and other self-aggregating proteins.

°Research Regulated by Other Federal Agencies: The Draft Policy states: "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained."
Recommendation: It would be very helpful to institutions if NIH could provide details on how this approval/clearance process will work, including:

- Specifying which federal agencies will have authority over various types of pathogens (e.g., Will USDA have jurisdiction over plant pathogens and genetically modified plants?) and what process institutions will need to follow to determine who has jurisdiction.
- Specifying which agency will have ultimate oversight of biomedical research in areas where multiple agencies (e.g., CDC, OSHA, USDA) have overlapping oversight responsibilities, and how that determination will be made.
- Clarifying the meaning of the phrase "approvals or other applicable clearances" and from which agency (i.e., NIH or another federal agency) institutions are expected to obtain these approvals/clearances.

Section II, Compliance and Enforcement: No comments.

Section II, Voluntary Compliance: No comments.

Section II, General Definitions Section

▪**Overarching Comments:** Several key definitions are overly broad, thus creating uncertainty regarding the Draft Policy's scope and undercutting NIH's stated goal of a risk-based biosafety policy. Additionally, the Draft Policy redefines terms that have well-established scientific meaning, reducing the clarity and consistency needed for effective policy implementation.
Recommendation: NIH should ensure that terms are defined in line with their common usage, and revise overly broad definitions to directly align oversight requirements with actual risks presented. Comments regarding specific definitions follow.

▪**Comments on Specific Definitions:**
°**Biological Agent:** As previously noted, the Draft Policy appears to assume that every biological agent constitutes a biohazard, and definitions clarifying the boundaries between these two terms should be provided. Additionally, the term "parasite," as used in this definition, would benefit from further clarification. For example, parasites could encompass mosquitos, ticks, lice, various helminths, etc., so if the definition is referring to intracellular parasites, it should state so. Similarly, the definition should address whether it encompasses ectoparasites that serve as vectors of disease transmission, as opposed to causing disease. Finally, the definition should also be clear as to how "opportunistic pathogens" that only affect very specific segments of the population should be addressed.
Recommendation: Revise this definition to address the points outlined above.

°**Biomedical Research:** In addition to being extremely broad, this definition has the potential to introduce instability and inconsistency, as it refers to "research on a topic that is within the mission of the NIH," and thus could change dramatically over short periods of time, depending on how Congress and the Executive Branch expand or curtail NIH's mission.
Recommendation: NIH should employ a static definition of biomedical research (e.g., "Research that is conducted to increase fundamental knowledge and understanding of the physical, chemical, and functional mechanisms of human life processes and diseases"[1]) that is not tied to, and does not change with, the scope of NIH's mission.

°**Emerging Agent:** NIH's definition of this term is at odds with the definition

[1] Definition of "biomedical research," NIH, Collection Development Guidelines of the National Library of Medicine (2019; updated Sept. 25, 2025).

used by scientists, biosafety, and public health professionals, who consider an "emerging agent" to be a known agent that is emerging as a cause of disease. Further, the NIH definition inappropriately equates a newly identified organism with a pathogen.

Recommendation: NIH should replace this definition with the more commonly accepted definition outlined above. If NIH retains the current definition, it should explicitly define what "newly identified in nature" means. For example, is "newly identified" limited to a new species or genus? Additional points that should be clarified in the definition include the following:

- How would chimeras and plasmids/viral vectors/replicon systems containing genetic material from different sources be viewed?
- How are prions and self-aggregating proteins viewed?
- Does the definition encompass synucleins and preformed fibrils, or other organisms/materials on which there is not yet consensus on whether they cause human disease or are just associated with such disease?

°Genetic Modification: The proposed definition of genetic modification significantly broadens the scope of items covered by the Draft Policy. Specifically, expanding the definition of "genetic modification" to include nucleic acids that can be translated, as well as the alteration of the genome using chemical or radiological means, is inconsistent with the NIH Guidelines' historical approach to oversight of research that introduces stable genetic modifications. Genetically modified organisms **do not** inherently present greater uncertainty. In fact, many genetically modified organisms are well characterized and **present less uncertainty** than their wild-type counterparts. Indeed, the level of uncertainty associated with an organism depends on multiple factors, including the nature of the modification, the amount and quality of available data, the resulting phenotype, and prior experience with the organism. Additionally, the Draft Policy's overly prescriptive approach to genetic modifications will result in inconsistent and duplicative oversight (e.g., overlap with FDA and existing laboratory oversight requirements) and adds little to no value in terms of improved biosafety. Rather, this approach has the potential to increase risk by causing the IBC and biosafety team to "spread themselves thin" by expending time and resources on lower-risk activities, instead of focusing on research presenting higher risks.

Recommendation: NIH's new approach to viewing all genetic modifications as suspect is inconsistent with NIH's intent to develop a risk-based policy. NIH should instead incorporate into the definition of genetic modifications a provision that limits IBC review and oversight to only those genetic

modifications that present specific risk characteristics and/or consequences based on available evidence.

°**Laboratory Research:** The Draft Policy includes the terms "laboratory settings" and "laboratory research," but only provides a definition for "laboratory research," which it defines in terms of containment levels.
Recommendation: As previously noted, NIH should include a definition of "laboratory settings," a term used in the Scope Section. Our organizations also recommend that NIH clarify whether the scope of the policy is based on "laboratory settings" or 'laboratory research." Finally, given that not all "laboratory research" requires containment levels, NIH should consider renaming this term as "laboratory research requiring containment" to avoid causing confusion among scientists and biosafety personnel who commonly understand this term as any research taking place in a lab setting.

°**Research Involving Biohazards:** This term is defined in the scope section, but it does not appear in the general definitions section.
Recommendation: For consistency, NIH should include "research involving biohazards" as a defined term within the general definitions section and specify how the term relates to the setting in which such research is performed, i.e., laboratory settings.

°**Toxins:** The Draft Policy defines a "toxin" as: "[a] protein or peptide produced by living organisms that causes harm in humans." Many biological molecules may cause harm under certain exposure conditions or at sufficiently high concentrations, but absent such conditions, they may be harmless. Although the risk assessment section of the Draft Policy appropriately accounts for factors such as potency, amount used, and intracellular accessibility, these concepts are absent from the definition. Additionally, the definition does not address the potential of exceptions for naturally occurring toxins (e.g., those produced by algae, use of cephalopods, etc.).
Recommendation: NIH should incorporate objective criteria (e.g., potency, exposure potential, quantity, biological activity) into the definition of "toxin," and consider using LD50 levels as a criterion for inclusion under the Draft Policy.

Section III, Roles and Responsibilities: See comments below.

Section III-A, Responsibilities of the Institution

▪**Applicability:** As previously noted, extending the Draft Policy to non-federally funded research conducted at institutions that receive any NIH funding appears to exceed the scope of NIH's regulatory authority.
Recommendation: NIH should identify the specific statutory authority supporting the extension of the Draft Policy to non-federally funded research conducted at institutions receiving NIH funding, and absent such specific authority, limit the scope of the Draft Policy to NIH-funded research. NIH should also provide greater clarity in this section and/or in the scope section regarding exactly what entities the policy applies to (e.g., affiliated hospitals, separately incorporated research institutes, subcontractors, international sites).

▪**Biosafety Assurance:** It is imperative that Authorized Organizational Representatives (AORs) specifically understand the criteria to which they are certifying through their execution of the Biosafety Assurance. It is also important that NIH conduct the assurance process in an efficient and streamlined manner that permits institutions to begin/continue covered research without undue delay.
Recommendation: NIH should clarify the following issues in the Draft Policy:

- Is the AOR certifying that the institution has established an adequate biosafety oversight program, or certifying compliance for every individual research activity and researcher covered by the policy?
- Describe the criteria NIH will use to approve, restrict, suspend, or withdraw an Assurance.
- Provide an anticipated turn-around time for NIH' approval of an assurance.

NIH should consider patterning the Biosafety Assurance process after the assurance processes in place at the HHS Office of Human Research Protections or at the Office of Research Integrity. Additionally, it would be helpful to institutions if NIH were to provide a draft template assurance document on which institutions can submit comments.

▪**IBC Training Responsibilities:** The Draft Policy states that an institution is responsible for ensuring appropriate training regarding laboratory safety and implementation for the IBC Chair and members, biological safety officer and other containment experts, principal investigators, and laboratory staff.
Recommendation: NIH should develop and provide role-based training resources that IBCs may use to satisfy these training responsibilities.

▪**Record-keeping requirements:** The Draft Policy vastly expands the scope of research requiring IBC review/oversight, resulting in a tremendous increase in IBC-associated records (both paper and electronic) that must be developed and retained, at substantial storage and archival costs.
Recommendation: NIH should consider implementing a more limited period of record retention. Given that the Draft Policy calls for the IBC to provide *de novo* review of each research protocol every three years, our organizations suggest that NIH cap the record retention period at two review cycles (six years), thus affording transparency, while reducing administrative burden.

▪**Public Posting of IBC Related Documentation:** The Draft Policy calls for the institution to publicly post "to the maximum extent possible" the following documents/information:

- Weblinks to publicly posted institutional biosafety procedures (including but not limited to documentation detailing the IBC roles, responsibilities, authorities, and processes for how biosafety risks are managed);
- A continuously updated IBC roster;
- IBC meeting minutes;
- Incident reports;
- Synopses of relevant staff trainings provided;
- Contact information for the IBC Contact, IBC Chair, and BSO (if applicable); and
- Information regarding whether the institution conducts research in a BSL3/ABSL-3 or BSL4/ABSL-4 laboratory, research with GDMOs, has a BSO, receives NIH funding, and/or has an externally administered IBC.

This approach fails to strike an appropriate balance between the need for public transparency and the need to protect the security of laboratory facilities, the security and privacy of biosafety personnel, and proprietary and confidential information associated with non-federally funded research that now falls within the scope of the Draft Policy.
Recommendation: Our member institutions understand the need for required documentation retention for agency inspection as appropriate under the Draft Policy. Nonetheless, the need for public transparency must be balanced against the goals and requirements of privacy laws (e.g., HIPAA, state privacy laws, collective bargaining agreements) and other policy concerns (e.g., protection of trade secrets, promoting a just and fair culture of incident reporting). With respect to incident reports, which often contain sensitive personal information, NIH should permit anonymized, aggregated reporting with identifiable information disclosed to appropriate governmental officials

only when there is a legitimate need to know (e.g., public health investigation). If NIH declines to adopt anonymized/aggregated reporting, it should not require the posting of any personally identifiable information except for the names and institutional information for the IBC Contact, IBC Chair and BSO.

NIH should also specify within the Draft Policy a de-identification standard (e.g., HIPAA standard) and specify what information can be redacted from records prior to public posting to protect the security and privacy of biosafety personnel and facilities and to safeguard proprietary and confidential information associated with non-federally funded research. Further, NIH should also exempt from posting any information related to processes and procedures developed to ensure the security of covered research and the facilities in which that research is conducted. Finally, the Draft Policy should be exempt from posting any information designated as confidential or proprietary by non-federal research sponsors.

Section III-B, Responsibilities of the Institutional Biosafety Committee

▪**Overarching Concerns:** Although NIH has expressed its intent to elevate and strengthen the role of the IBC and the BSO, the Draft Policy does not clearly delegate to those parties the specific authorities necessary to carry out those responsibilities.
Recommendation: NIH should clearly delineate within the Draft Policy specific authorities of the IBC and BSO (e.g., ability to take timely action to address significant biosafety concerns, suspend research protocols, etc.). NIH should also include provisions within the Draft Policy that ensure the IBC's independent decision-making authority akin to the independent authority of IRBs and IACUCs (e.g., institution cannot reverse IBC's non-approval or suspension of a protocol).

▪**IBC Membership**: No comments.

▪**IBC Functions:** See comments below.

▪**First Sentence of Section ("The IBC, or its delegate as applicable, is responsible for"):** The first sentence's reference to "[t]he IBC, or its delegate as applicable" is confusing.
Recommendation: NIH should clarify whether the term "or its delegate" refers to an individual or subgroup of IBC members assigned to conduct "delegated reviews" under Section IV-3.

- **First Bullet Point:**
  - **Clause (3)("in cases of research involving. . . "):** The concerns noted in clause (3) relating to research involving "human subject research participants" are also applicable to animal research.
    Recommendation: Delete the text that reads "in cases of research involving human research participants."

  - **Third Sentence ("IBC oversight may conclude . . . "):** Shedding may continue after the last dose of a product is administered to human research participants, so it is unclear as to why IBC oversight should end at that point.
    Recommendation: Delete the third sentence ("IBC oversight may conclude after the last participant is administered the final dose of product") and modify the fourth sentence to read as follows: "IBCs should establish appropriate endpoints for oversight based on their biosafety assessment of the proposed research."

  - **First Sub-Bullet Point ("No member of the IBC . . . "):**: It is unclear as to who has the responsibility for determining whether an IBC member has a conflict of interest.
    Recommendation: NIH should include a statement that the IBC is empowered to establish its own processes and procedures for soliciting information from members regarding possible conflicts of interest and determining when such conflicts exist and require member recusal.

- **Second Bullet Point ("Taking IBC meeting minutes. . . "):** Requiring approval of IBC minutes "no later than [the IBC's] next convened meeting," places excess administrative burden on IBCs that meet frequently and review large numbers of protocols. Indeed, one COGR member institution has estimated based on current meeting-minute preparation time and the template content that it will be required to hire a full-time employee just to fulfill the Draft Policy's IBC meeting minutes requirements.
  Recommendation: NIH should extend the period for approval of IBC meeting minutes to "no later than ninety (90) days after the meeting at which the minutes were taken."

- **Third Bullet Point ("Notifying the PI when . . . "):** The Draft Policy calls for "de novo registration submission and review" at least every three years, however, NIH does not provide any rationale for requiring de novo review for all protocols or for selecting a three-year period, as opposed to four or five-year

period. If the Draft Policy is intended to be risk-based, then the period for review and re-registration should be based on risk posed by the research in question, as determined by the IBC.
Recommendation: NIH should modify the Draft Policy to permit the IBC to establish the re-registration period based on the risk posed by a specific research protocol. NIH should also empower the IBC to provide a re-review/re-registration grace period of up to 90 days to accommodate circumstances in which the IBC cannot complete its review within the specified period.

Alternatively, if NIH maintains the strict three-year re-registration/re-review period, it should specify within the policy what the status of a protocol is that (a) has not been reviewed/approved within the three-year period; or (b) has been reviewed but not approved within the three-year period because protocol changes are required. Additionally, NIH should clarify whether the three-year review requirement will apply prospectively (i.e., to protocols first approved by the IBC after the Draft Policy is implemented), or retrospectively (i.e., to protocols first approved by the IBC prior the Draft Policy's implementation), and if the latter, the date by which existing IBC-approved protocols must receive de novo approval.

▪**Fifth Bullet Point ("Petitioning NIH for determination of the minimum . . ."):** The circumstances in which the petition process is to be used, and the operational details of the process are unclear.
Recommendation: NIH should clarify this provision in the following respects: (a) specify whether the petitioning mechanism is limited to human pathogens; (b) allow for the possibility that no biocontainment level will be required in the case of low-risk agents; (c) establish a timeline by which NIH will address the petitions that it receives; and (d) address how IBCs should handle cases in which the organisms in question cannot be identified past the genus level.

▪**Seventh Bullet Point ("Periodically reviewing approved . . ."):** It is unclear whether the "periodic review" specified in this provision is to be carried out in addition to the de novo review.
Recommendation: NIH should clarify if the periodic review is required in addition to the three-year de novo review, and if so, provide additional details on expectations for periodic review, including specification of the protocol sections/elements that require review. Along these lines, is periodic review necessary with a three-year de novo review requirement? If the 3-year de novo review requirement is maintained, NIH should consider the USDA's review

approach, which requires 3-year de novo review, but removed a previous requirement for annual continuing review. [9 CFR §2.31].

▪**Eighth Bullet Point ("Adopting plans which include . . . "):** The Draft Policy is unclear as to whether the IBC must formally adopt any institutional emergency response plans, many of which address areas outside of the IBC's scope.
Recommendation: NIH should clarify whether the IBC must formally adopt all institutional emergency response plans (i.e., in a manner similar to that in which protocols are approved), or whether IBC or BSO review of/consultation regarding the portions of institutional emergency response plans impacting IBC-regulated areas is sufficient.

▪**Tenth Bullet Point ("Reporting certain incidents . . ."):** The first sentence of this section states that reporting is required for incidents that pose a significant risk to human health. However, this modifying phrase is absent in the description of individual incidents that must be reported, thus creating confusion. For example, why would the lack of registration of a human cell line require 24-hour reporting, particularly if a lab were functioning at BSL2? Further, under the fourth sub-bullet point ("Any incidents involving exposures at BSL-2/ABSL-2) . . ."), it is unclear whether minor exposure to an agent not known to cause disease or a non-treatable BSL2 exposure requires reporting. Overall, the lack of clear reporting criteria and thresholds in this section will result in inconsistent reporting practices. For example, a non-biological occupational injury (e.g., back strain) that occurs inside a BSL-3 laboratory could technically be considered a "incident at a BSL-3 facility," but have no biosafety implications. Finally, the term "adventitious agent" (as used in the last sentence of this section) is undefined.
Recommendation: NIH should empower the IBC to determine in its policies and procedures which types of reported incidents require committee-level review, and which can be handled via reporting to and review by the BSO. Further, our organizations urge NIH to explicitly state that incidents are reportable to NIH only when the IBC determines that they are biologic in nature and pose a significant risk to human health, by making the following modifications to this section:

- **First Sentence:** Modify this sentence to read as follows: "Reporting certain incidents to NIH that the IBC has determined are biologic in nature and pose a significant risk to human health using the required reporting template.

- **Third Sentence:** Modify this sentence to read as follows: "This includes the incidents involving the factors listed below when the IBC has determined such incident is biologic in nature and poses a significant risk to human health:"
- **Fourth Sub-Bullet Point:** Clarify whether exposure to an agent not known to cause disease or untreatable exposures at BSL-2/ABSL-2 that the IBC has determined do not pose a significant risk to human health are reportable.

NIH should provide examples that clearly distinguish reportable and non-reportable events to promote consistent interpretation and reporting. Finally, NIH should include a definition for "adventitious agents" in the General Definitions section.

▪**Eleventh Bullet Point ("Reviewing certain lower-risk incidents . . . "):** If NIH intends for this policy to be a risk-based policy and to empower the IBC and BSO to provide appropriate oversight, it is unclear (1) why any incidents at BSL-1/ABSL-1 require mandatory reporting to/review by the IBC, as opposed to being handled via interaction with the BSO, with reporting to the IBC as the BSO determines is appropriate in accordance with institutional/IBC policies and procedures.

Recommendation: NIH should modify this bullet point and its two sub-bullet points to remove any references to BSL-1/ABSL-1 and to instead include the following statement:

> Incidents at BSL-1/ABSL-1 that (a) do not involve recombinant technology; and/or (b) that involve minor spills of low-risk agents that do not breach containment and that are properly cleaned and decontaminated in accordance with institutional policies and procedures, shall be handled by the researcher in conjunction with the BSO. The BSO shall report to the IBC any such incidents that require reporting under applicable institutional and/or IBC policies and procedures.

▪**Twelfth Bullet Point ("Posting all incident reports .. . . "):** This provision is unclear as to whether public posting is required for incidents that are not required to be reported to NIH.

Recommendation: NIH should modify the first sentence of this provision to read as follows: "Posting of all incident reports for those incidents that are required to be reported to NIH on a public-facing webpage on the website of the institution, using the required incident reporting template."

Biological Safety Officer: As written, the Draft Policy increases the BSO's responsibilities without a corresponding increase in authority or recognition of the subject matter expertise necessary to carry out the BSO's duties.
Recommendation: NIH should define the BSO's authority (e.g., authority to stop work conducted under an IBC approved protocol that poses a significant risk to human health), in addition to detailing responsibilities. Alternatively, the Draft Policy should make clear that the institution is empowered to delegate such authorities to the BSO as are necessary to carry out the responsibilities listed in the Draft Policy. Additionally, NIH should detail any minimum qualifications/competencies that it expects the BSO and/or "other official" assigned to take on these responsibilities to possess. Finally, it was noted that NIH eliminated large scale work (i.e., >10 L) as an independent trigger requiring a BSO, and questions were raised by our members as to whether this was an intentional omission.

Section, III-C, Responsibilities of the Principal Investigator: This section should make clear that the PI's responsibilities must be carried out within the framework of IBC and institutional policies and processes.
Recommendation: NIH should modify the first sentence of this section to read as follows: "The responsibilities of the PI include following all institutional and IBC policies and procedures including those governing the following duties:"

Section III-D, Responsibilities of the National Institutes of Health (NIH): The Draft Policy lists NIH responsibilities, but it lacks processes that NIH will follow in carrying out these responsibilities, including applicable timelines. Additionally, this section fails to include clear mechanisms for how NIH will directly communicate with assured institutions and registered IBCs.
Recommendation: NIH should provide details on the processes that it will follow in carrying out its responsibilities under this section, including associated timelines, particularly with respect to when NIH will provide decisions regarding containment levels, Biosafety Assurances, and incident reports. NIH should also include within its listed responsibilities an obligation to directly communicate with all assured institutions and registered IBCs regarding proposed policy changes and interpretations and provide ample time for comments. Additionally, NIH should establish a central webpage where all containment and other IBC-related determinations are posted.

Section IV, Categories of Oversight for Research Based on Risk: See comments below.

Section IV-1, Research that Requires NIH and IBC Approval Before Initiation: This section of the Draft Policy specifies the research and requests that must receive NIH approval, but it fails to provide details regarding the operational process for making these requests or how NIH will conduct its scientific review. Further, this section lacks any information concerning the timeline for decision-making by NIH, as well as any circumstances that warrant expedited decision-making.

Recommendation: NIH should provide templates outlining the information to be provided to the agency in connection with (a) review of research involving emerging/novel/zoonotic agents for which the risk group (RG) classification or minimum containment level is not available in the BMBL; (b) initial requests to lower containment for research involving wild type or genetically modified RG3 or RG4 biological agents; and (c) initial requests to lower containment below BSL-2 for research involving gene drive modified organisms (GDMOs). Additionally, NIH should consider initially spelling out the acronym "GDMO" and providing a definition for this term.

To assist institutions and IBCs in better understanding and preparing for the determination process, NIH should also detail how it will conduct its scientific review process, including a description of who will be involved in the process and their subject matter expertise, along with the objective assessment criteria that will be employed. Additionally, NIH should set forth expected review periods, including circumstances that justify expedited review requests, along with a process for IBCs/institutions to obtain status updates, and an escalation mechanism for when a determination is delayed beyond the stated period. Finally, NIH should also clarify whether an institution may proceed with research under interim containment requirements established by the IBC, pending receipt of the NIH determination.

Section IV-2, Research that Requires IBC Review and Approval Before Initiation: The research category listed under the fourth bullet point – "Research with primary cells that may be contaminated by adventitious agents" – is overly broad and includes research posing low-level risks that do not warrant mandatory review by the full IBC. For example, this category encompasses human primary cells, human tissues, human blood-derived materials, non-human primate tissues, and other primary materials that are routinely handled using universal precautions and/or following institutional exposure control plans/occupational health programs and OHSA requirements related to bloodborne pathogens.

Recommendation: As previously noted, NIH should include a definition for the

term "adventitious agents." Additionally, NIH should limit the scope of this category to primary cells with known or reasonably suspected contamination by adventitious agents that require specialized containment or response measures beyond universal precautions/OSHA bloodborne pathogen requirements. If NIH rejects these recommended limitations, it should, at the very least, allow for delegated review of activities falling within this category that are routinely conducted in accordance with established institutional controls.

Section IV-3, Research that Requires Review and Approval Before Initiation and May be Delegated to an Individual or Subgroup of IBC Members: The Draft Policy (a) omits the category of Exempt Experiments included in Section III-F of the current NIH Guidelines; (b) omits the category of low-risk experiments requiring only notice to the IBC under Section III-E of the NIH Guidelines; and (c) omits any exemption for transgenic rodents housed at ABSL-1. Instead, the Draft Policy requires delegated review for these low-risk activities resulting in a vastly increased IBC workload and unnecessarily hampering research activities without a corresponding increase in safety benefits. Rather than focusing on allocating IBC efforts and resources to higher-risk activities, the Draft Policy directs limited IBC, institutional, and agency resources to the review of research activities that pose so little risk that they would not even fall within the ambit of a truly risk-based policy.
Recommendation: As NIH has stated, a major goal of the Draft Policy is to establish a risk-based regulatory approach. Accordingly, NIH should retain the categories of exempt experiments and experiments requiring only notice to the IBC simultaneously with initiation as described in Sections III-E and III-F of the current NIH Guidelines.

Section V, Risk Assessment and Mitigation for Research Involving Biohazards: As previously noted the Draft Policy appears to inappropriately equate the terms "biohazard" and "biological agent," by requiring a risk assessment for "research involving ***biohazards***," but only providing a definition of the term "***biological agent.***" Additionally, the Draft Policy significantly expands the categories of research that fall within its scope, but it provides limited operational guidance that IBCs and institutions can use to ensure that mandated risk assessments are performed in an objective and consistent manner. The Draft Policy includes factors to consider in risk assessments, but it lacks any decision-making frameworks that IBCs can use when evaluating these risks and developing risk mitigation strategies. Finally, the use of the word "manipulation" in the phrase "Manipulations of the biohazard," is

confusing because manipulation can be used to refer to either changing the characteristics of the agent (which is addressed elsewhere in the policy) or the physical handling of the agent, which is the topic of this section.
Recommendation: As previously noted, NIH should provide a definition of the term "biohazard" that distinguishes it from "biological agent." NIH should also develop and provide additional tools that IBCs can use to promote objective and consistent risk assessments such as frameworks discussing how risks and benefits should be weighed and evaluated, sample containment determination examples, sample risk mitigation plans, case studies, and FAQs. Finally, NIH should replace the word "manipulations" with "handling."

Section V-A, Requirements and Consideration for Risk Assessment of the Characteristics of the Biohazard: No comments.

Section V-B Requirements and Consideration for Risk Assessment for Genetically Modified Biological Agents, Cells, or Organisms: No comments.

Section V-C, Requirements and Considerations for Risk Assessment for Synthetic Biological Agents or Emerging Technologies: No comments.

Section V-D, Requirements and Considerations for Risk Assessment of Manipulations of Biohazards: As previously noted, to avoid confusion, NIH should replace the word "manipulations" in this section with "handling."

Section V-E, Risk Mitigation Strategies and Laboratory Containment: As previously noted, in some cases GDMOs may be more stable than wild-type organisms, and thus it is unclear why the Draft Policy requires a minimum of BSL-2 for all research involving GDMOs.
Recommendation: NIH should delete the minimum BSL-2 containment requirement for GDMOs and empower IBCs to set an appropriate containment level based on the characteristics of the GDMO.

IBC Meeting Minutes Draft Template: The meeting minutes templates is overly detailed and prescriptive and serves only to impede minutes preparation by requiring reiteration in the minutes of details that are already included in other documentation (e.g., standard operating procedures, research protocols). Further, given that the Draft Policy encompasses non-NIH funded research conducted at institutions that receive NIH funding, the Draft Policy inadequately addresses the types of redactions that are appropriate in cases in which an institution's conduct of non-NIH funded research is subject

to confidentiality and non-disclosure obligations. Finally, the required level of detail in the minutes makes it extremely difficult, if not impossible, for institutions to meet the Draft Policy's deadline for having minutes prepared by the next convened IBC meeting, particularly at institutions that have multiple IBCs meeting frequently.

Recommendation: Our organizations urge NIH to withdraw the required template approach, and instead follow the approach to meeting minutes adopted by the Common Rule, and require only that the institution or IBC "prepare and maintain adequate documentation of all [IBC] activities" including "Minutes of [IBC] meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the [IBC]; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." [*See*, 45 CFR §46.115]. If NIH maintains the template approach, the agency should consider making the following changes to the template and process for keeping minutes:

- **Timing:** Allow for 90 days to prepare meeting minutes.
- **Redaction Principles:** The NIH's redaction standards do not take into account the fact that the Draft Policy encompasses research that NIH does not fund and that is frequently being conducted pursuant to a contract with a private entity that impose confidentiality and non-disclosure obligations on the institutions carrying out the research. These confidentiality and non-disclosure requirements often include proprietary or pre-patent information that is critical for IBC review, but the public disclosure of which has significant financial and legal implications for the sponsor. Our organizations remain concerned that NIH's inclusion of non-NIH funded research within the scope of the Draft Policy is inappropriate and without statutory authority. Should NIH continue with this approach, our organizations urge the agency to recognize within the template that institutions may cite contractual standards governing non-NIH funded research as the basis for redactions made in meeting minutes. To do otherwise would constitute undue interference with an institution's ability to contract with private entities to carry out research, merely because the institution accepts NIH funding on unrelated projects.
- **Incident Review**: It should be sufficient to include within meeting minutes the same level of detail regarding incidents that is required in public posting of those incidents.

Draft Incident Reporting Template: As with the minutes template, the incident reporting template is overly detailed and prescriptive, and requires the disclosure of information that may compromise the privacy of an individual involved in an incident and the security of research activities. Further, the requirement to publicly post such detailed information, including "root cause analysis," serves to discourage incident reporting and goes against efforts to replace a "blame culture" of incident reporting with a "fair and just culture" approach that facilitates and supports self-reporting.

Recommendation: Our organizations recommend that NIH abandon the mandated template (which is not in effect for either IRBs or IACUCs) and permit anonymized aggregated incident reporting. Alternatively, NIH should require institutions to only report on incidents that pose a significant risk to human health by supplying sufficient detail to provide notice of the event and follow-up corrective actions taken. If NIH retains the proposed incident reporting template, the agency should consider making the following changes:

- **Required Reports:** NIH should reference the provisions of Section III-B of the Draft Policy with respect to the incidents that must be reported instead of repeating this information in the template. The repeated information adds confusion, not clarity (e.g., "administrative failure" description is too broad to be helpful). Further, as previously noted, NIH should limit the incidents required to be reported to those that the IBC determines are biologic in nature and pose a significant risk to human health. This point should be made clear in the form instructions and in the section on incident information. NIH should also clarify if the reporting template is only used for reports to NIH, or if it must be used for internal institutional reporting as well.
- **PI's Name and Grant Information:** Remove the requirement for providing the PI's name, particularly if public posting is required. In labs that have only one or two workers, the posting of the PI's name could lead to identification of the person involved in the incident. For the same reason, grant information that can be used to identify the PI also should be removed prior to publication.

Conclusion: Our organizations appreciate the opportunity to provide comments on the Draft Policy. Our member institutions support robust biosafety review and oversight but have expressed concerns that the Draft Policy tilts too far in the direction of requiring numerous and complicated controls for low-risk research. Such an approach does not serve the cause of increased biosafety because it misallocates ever-more limited resources away

from the oversight of higher-risk activities, while unnecessarily burdening the conduct of low-risk activities. Accordingly, NIH should consider recalibrating its approach by modifying the Draft Policy to better enable IBCs and BSOs to provide independent, risk-based review and oversight. The recommendations expressed above will help to foster such an approach.

Finally, our organizations request that prior to the publication of a final policy, NIH will post for comment a revised draft of the policy that includes a summary of the comments it received and its basis for accepting/rejecting those comments.

If you have any questions regarding this transmittal, please feel free to email the following association representatives:

> **AAU:** Lizbet Boroughs, Senior Associate Vice President for Government Relations and Public Policy at lizbet.boroughs@aau.edu
>
> **APLU:** Deborah Altenburg, Vice President for Research Policy & Advocacy at daltenburg@aplu.org.
>
> **COGR:** Kristin West, Director, Research Ethics & Compliance at kwest@cogr.edu.

Sincerely,



Lizbet Boroughs
Senior Vice President for
Government Relations & Public Policy
AAU



Deborah Altenburg
Vice President for Research,
Policy & Advocacy
APLU



Kristin West
Director, Research Ethics & Compliance
COGR

269. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Definition of "biohazards" requires significant clarification and examples
The Policy defines research involving biohazards as "research involving known or potential risk to human health and any of the following:
1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above."
NIH should provide examples to clarify the phrase "known or potential risk to human health." This phrasing as provided is far too broad and open to interpretation. What level of risk would be considered significant, or is any risk, no matter how small, subject to the Policy's oversight? For example, wild-type Risk Group 1 agents are excluded from the Policy, presumably because of a lack of risk to human health; but it is unclear if a genetically modified Risk Group 1 agent expressing only a reporter transgene would be considered a biohazard under the Policy and who is meant to make that determination. The existing NIH Guidelines contain specific Exemptions where the agents in use do not present a significant risk to health or the environment (e.g., E. coli K-12, S. cerevisiae, certain activities involving transgenic rodents, etc). It is unclear if these organisms would be Exempt when genetically modified under the new Policy. Similarly, it is unclear if all primary cells and cell lines (including, for example, murine or insect cells) are included within the Policy scope, or only those that harbor human infectious agents.

Definition of "toxin" requires refinement
The Policy defines Toxin as "A protein or peptide produced by living organisms that causes harm in humans." This definition is far too vague. First, not all biological toxins are proteins or peptides (e.g., T-2 toxin); are such toxins excluded from the policy's oversight? Second, describing a toxin as any protein that "causes harm in humans" includes other protein classes that are not toxins (e.g., oncogenic proteins, allergens). NIH should refine this definition and should include reference to a practical LD50, as the scientific standard for classifying toxicity.

Definitions of “emerging agent or organism” and “zoonotic” require clarification
The definitions of “emerging agent or organism” and “zoonotic” require significant clarification and examples to ensure they are reasonably applied, especially given the Policy’s requirement for NIH review and input for any research involving an emerging or zoonotic agent without a current RG or containment level classification. As written, the definitions for these agent categories are extremely broad and would be difficult to apply in practice. For example, would studies that involve screening environmental samples for previously unidentified organisms or strains require NIH review for each strain identified? At what point in such research would NIH review be required: at the initiation of the work because there is a chance of identifying a new agent, or only after the agent has been fully characterized and deemed both novel and potentially pathogenic? What constitutes a “newly identified” agent? Must it be a species that has not been published in literature? What about new strains of previously known species? What qualifies as “reasonable suspicion” of transmission from animals to humans? Such questions about practical application of the definitions limit their utility and may lead to overwhelming need for NIH input on relatively low risk (BSL-2) studies. We suggest that NIH limit the definitions to organisms with potential for serious or lethal human disease, as assessed by the PI in consultation with the IBC. We also request clarification regarding expected oversight for studies involving screening or culture of unknown organisms from clinical or environmental samples.

Clarify “biomedical research” definition and supply a definition of “research”
The Policy’s definition of “biomedical research” under its scope is written as “research on a topic that is within the mission of the NIH, including applicability to: research supported by NIH, and non-NIH funded research that is conducted at an institution that receives any NIH funding.” NIH should update the definition to address the following gaps.
First, NIH should clarify what is meant by “non-NIH funded research”. As written, it is unclear if this refers to any research that is not funded by the NIH, or any funded research that is not funded by the NIH.
Second, NIH should take this new Policy implementation as an opportunity to clarify a definition of “research.” Biohazards are used in many different non-research projects, such as teaching, clinical testing, or manufacturing. While safety is necessary for all biohazard handling, the oversight structures of this Policy are specific to research and should be clarified as such with a definition of research. As a model, human subjects research requiring Institutional Review Board (IRB) review has clear and established definitions of both “human subjects” and of “research”.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Refining definitions is necessary to ensure oversight is calibrated to risk
As stated previously, NIH must refine and provide examples for terms including “biohazards”, “emerging agents”, and “zoonotic” to ensure it is clear what level of human health risk is truly relevant to the new Policy. This clarification should help to ensure that the tiered oversight structure in the new Policy is properly calibrated to risk. Additional terminology that is unclear or appears to require excessive review is listed below. NIH should provide examples of what falls within these terms and what does not for consistent application of the Policy:
- “Primary cells that may be contaminated with adventitious agents”: By definition, primary cells are less well-characterized than other cell lines. Primary cells collected from laboratory rodents that have not been treated with infectious agents should not require full IBC review.
- “Transgenic organisms”: Clarify the difference between “genetically modified” and “transgenic” for oversight purposes.

- “Reporter or low-risk transgenes”: Provide examples for consistent implementation.
- “Well-characterized cell lines”: What qualifies as “well-characterized”?

3. Continued utility of Risk Groups: Risk Group lists must be frequently updated and publicly shared by NIH

Reliance on Risk Groups as a baseline for risk assessment is acceptable, as this practice is already widespread and allows a base level of consistency between institutions. However, because the Policy continues to depend on Risk Groups and requires NIH input for Risk Group determination, the NIH must publicly share and frequently update Risk Group lists based on requests for input from institutions. This practice of sharing all Risk Group determinations publicly at the federal level will promote consistency across institutions, while reducing administrative burden at both institutional and federal levels for review of identical agents from multiple institutions.

Clarify the role of the BMBL as an advisory document

The existing NIH Guidelines contain requirements for various biosafety levels, which the new Policy removes in favor of aligning biosafety levels with those described in Biosafety in Microbiological and Biomedical Laboratories (BMBL). We support this change as it helps to reduce redundancy and/or conflict between biosafety level definitions applied by different agencies. However, we believe the new Policy should clarify its expectation in use of the BMBL as an advisory document. The BMBL was not written as a policy requirement. While it provides an excellent framework for best practice, institutions should be able to adapt and deviate from the BMBL when justified and appropriate for their specific circumstances.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public posting of individual incident reports will create privacy issues, increase administrative burden, and reduce reporting rates.

We have significant concern regarding the requirement for public posting of individual incident reports, especially given the level of detail included in the required Incident Reporting template and the minimal immediate value in public reporting on low-risk incidents. While we agree with the aim of transparency and the value of consistency in reported data across institutions, we do not see these values truly enhanced by public reporting of individual incidents on institutional websites for the following reasons:

- The Policy includes development of a National Biosafety Data and Safety Analysis Center where all NIH-reportable and voluntarily submitted incident reports would be aggregated, de-identified, and analyzed. This Center provides true value in advancing the metascience of biosafety by centralizing incident data. Institutionally posted incident reports do not add to that goal.
- Short summaries of incidents are already included for required public posting in IBC Meeting Minutes according to the required template. If the goal of posting individual incident reports is to ensure public awareness, posting of IBC Meeting Minutes already meets this need, making posting of individual Incident Reports redundant.
- Regardless of the ability to redact names from incident reports, we are concerned that posting of individual incident reports will violate privacy of those involved. At smaller institutions or in smaller research labs, listing an individual’s job title effectively identifies that individual. We have significant concern about the implications of this for protecting individual health information.

- Instead of providing value, we strongly suspect that researchers may view incident report posting as punitive and that this requirement will significantly decrease the number of incident reports notified to biosafety programs, thus directly reducing biosafety programs' ability to promote the safety that the Policy aims to support.

We instead suggest an alternative approach to strike a balance between immediate transparency, institutional administrative burden, and advancement of biosafety:

- If the goal of incident report posting is to improve biosafety and increase public transparency, we believe the required reporting structure for NIH-reportable incidents and collection of data in the National Biosafety Data and Safety Analysis Center, without institutional posting of individual reports, meets this need for NIH-reportable incidents.
- Non-NIH-reportable incidents are lower risk, thus making immediate posting for public transparency of limited value and a potentially high administrative burden. We propose that institutions instead be required to post or provide to NIH an annual summary of these lower risk incidents at their institutions. This would be similar to annual reporting of OSHA recordable incidents. This process would remove the privacy concerns around posting individual reports, while maintaining a focus on transparency and accountability to the public and encouraging institutions to periodically evaluate their incident data for trends, thus promoting continuous improvement.

24-hour notification for compliance violations is not reasonable or valuable

The new Policy codifies immediate (i.e., within 24 hours) notification for certain types of incidents, which has been the expected practice under the existing NIH Guidelines for high-risk incidents. However, the new Policy stipulates required immediate notification for all NIH-reportable incidents, including "any compliance violations at any BSL/ABSL". Compliance violations that do not also involve a serious incident should require the standard 30-day reporting only. This reduces the administrative burden on reporting these cases when there is no immediate risk resulting from the violation, while maintaining a standard of reporting all compliance violations to the NIH.

Incident Reporting Template should not require funding information

The Incident Reporting Template includes fields for NIH grant number, NIH funding institute, and NIH program officer. We do not see the value in including this information in incident reports and suspect it will be perceived as punitive, leading to fewer incident reports and undermining the safety culture that the Policy aims to support.

IBC Meeting Minutes Template should be recommended, not required

Requiring a specific IBC Meeting Minutes template creates an administrative burden and compliance challenge that does not directly support safety or transparency. While we can see value in a shared format across institutions, this value does not outweigh the administrative burden of updating existing, functional systems to match a specific template. We suggest instead that the Meeting Minutes Template be provided as a recommended resource, as was done in 2025 when the requirement for public posting of meeting minutes went into effect. To support the recommended template, there should also be a clear list of the minimum required information to help institutions meet compliance requirements. No other similar compliance committee (e.g., IRB, IACUC) has a required meeting minutes template at the federal level.

6. Other feedback relevant to this resource: Implementation timeline is too short

The 6-month implementation timeline is far too short. The Policy significantly expands scope from the

prior NIH Guidelines, and effective implementation will require institution-wide policy changes, development of new procedures and forms to match required templates, and re-education of campus stakeholders. As a public academic institution, many of our campus processes are influenced by fiscal or academic year calendars, making a timeline of less than one year impractical. We request at least one year, as has been typical for other new federal biosafety policies in recent years.

Supporting materials should be provided for Biosafety Assurance documentation
NIH should supply an example of the Biosafety Assurance documentation to aid institutions in meeting this new requirement. This resource would be akin to the Assurance Sample Document provided by OLAW for verifying compliance with the Policy on Humane Care and Use of Laboratory Animals.

270. Benaroya Research Institute

I am responding: On behalf of an organization

Name:

Name of Organization: Benaroya Research Institute

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Immune Disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Concern with expectations for minutes approval no later than the next convened meeting
This expectation removes flexibility that IBCs and administrators need to accommodate researchers. Two scenarios illustrate the burden.
1. When the IBC convenes an ad hoc meeting to approve time-sensitive research ahead of its regular schedule, administrators have less time to finalize the previous meeting's minutes.
2. When a regularly scheduled meeting has a full agenda with multiple registrations or complex amendments, IBCs often defer minutes approval so that all research items can be reviewed in the allotted time.
We respectfully request NIH to consider the following:
1. A fixed deadline for minutes approval adds administrative burden without advancing the safe, responsible, and secure conduct of research.

Draft Incident Reporting Template
There are numerous areas needing further details or clarification including:
1. Who is responsible for completing the form: the PI, the IBC, or other institutional staff.
2. What information is required for immediate reporting.
3. What type of incidents fall into this “significant risk to human health” category.
4. Reportable incidents include "administrative failures" but does not define the term, provide examples or explain when such failures must be reported. Rather than referring broadly to a section of the Policy, the template should use the Policy's own language so it’s clear what is immediately reportable.

5. The draft does not make clear whether NIH-reportable incidents or all incidents including lower-risk incidents require reporting to NIH or posting on the institution's website.
6. A template asks whether the incident occurred during NIH-funded research and requests the grant or contract number. Because laboratory personnel may perform tasks that support multiple funded projects, or none, attributing an incident to a single award may not always be straightforward. We request that NIH clarify how institutions should respond in these cases.
We respectfully request NIH to consider the following:
1. IBCs post only those incidents that pose significant risk to human health.
2. There is clear responsibility surrounding incident reporting.
3. To provide a definition and examples of what constitutes “significant risk to human health”.
4. No incident reporting is required if administrative failures do not pose significant risk.

Draft Meeting Minutes Template
NIH states that minutes should serve as the institution's record of IBC proceedings and document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities. The level of detail the template requires goes well beyond that purpose, and it is not realistic for institutions whose administrative staff serve in multiple roles and are not biosafety subject-matter experts. For example:
1. Several sections duplicate information already captured in the IBC application, (e.g., project overview, risk assessment, discussion, training).
2. Staff must copy content into the minutes which adds effort without oversight value.
3. Duplicate information is entered when projects are approved through delegated review and would be reported both in the review of prior business section and in the project-specific overviews.
We respectfully recommend NIH to consider the following:
1. Minutes are meant to summarize what the IBC reviewed and the actions it took, demonstrating that it fulfilled its duties. They are not meant to recreate the meeting or serve as a transcript.
2. Allow IBCs to continue with their own minutes template summarizing the project, discussion, action and oversight responsibilities without requiring administrators to reproduce protocol applications in the minutes.

6. Other feedback relevant to this resource: N/A

Uploaded File: Feedback-on-Draft-NIH-Biosafety-Policy-for-Research-Involving-Biohazards-13-Oct-2026.docx

Description: Feedback on Draft Policy

Benaroya Research Institute

Submitted by: Benaroya Research Institute
Sarah Valenti, JD - Research Protections Manager
Cheryl Weaver, BA – Research Integrity & Safety Director

Date: 14-October-2026

Subject: Response to the Draft NIH Biosafety Policy for Research Involving Biohazards

Please consider our response to the Draft NIH Biosafety Policy for Research Involving Biohazards. We've broken the comments down into 3 sections for easier review.

Minutes approval no later than the next convened meeting

This expectation removes flexibility that IBCs and administrators need to accommodate researchers. Two scenarios illustrate the burden.

1. When the IBC convenes an ad hoc meeting to approve time-sensitive research ahead of its regular schedule, administrators have less time to finalize the previous meeting's minutes.
2. When a regularly scheduled meeting has a full agenda with multiple registrations or complex amendments, IBCs often defer minutes approval so that all research items can be reviewed in the allotted time.

We respectfully request NIH to consider the following:

1. A fixed deadline for minutes approval adds administrative burden without advancing the safe, responsible, and secure conduct of research. If a timeframe is needed, we request 30 days after approval by the IBC to be better managed.

Draft Incident Reporting Template

There are numerous areas needing further details or clarification including:

1. Who is responsible for completing the form: the PI, the IBC, or other institutional staff.
2. What information is required for immediate reporting.
3. What type of incidents fall into this "significant risk to human health" category.
4. Reportable incidents include "administrative failures" but does not define the term, provide examples or explain when such failures must be reported. Rather than referring broadly to a section of the Policy, the template should use the Policy's own language so it's clear what is immediately reportable.

5. The draft does not make clear whether NIH-reportable incidents or all incidents including lower-risk incidents require reporting to NIH or posting on the institution's website.
6. A template asks whether the incident occurred during NIH-funded research and requests the grant or contract number. Because laboratory personnel may perform tasks that support multiple funded projects, or none, attributing an incident to a single award may not always be straightforward. We request that NIH clarify how institutions should respond in these cases.

We respectfully request NIH to consider the following:

1. IBCs post only those incidents that pose significant risk to human health.
2. There is clear responsibility surrounding incident reporting.
3. To provide a definition and examples of what constitutes "significant risk to human health".
4. No incident reporting is required if administrative failures do not pose significant risk.

Draft Meeting Minutes Template

NIH states that minutes should serve as the institution's record of IBC proceedings and document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities. The level of detail the template requires goes well beyond that purpose, and it is not realistic for institutions whose administrative staff serve in multiple roles and are not biosafety subject-matter experts. For example:

1. Several sections duplicate information already captured in the IBC application, (e.g., project overview, risk assessment, discussion, training).
2. Staff must copy content into the minutes which adds effort without oversight value.
3. Duplicate information is entered when projects are approved through delegated review and would be reported both in the review of prior business section and in the project-specific overviews.

We respectfully recommend NIH to consider the following:

1. Minutes are meant to summarize what the IBC reviewed and the actions it took, demonstrating that it fulfilled its duties. They are not meant to recreate the meeting or serve as a transcript.
2. Allow IBCs to continue with their own minutes template summarizing the project, discussion, action and oversight responsibilities without requiring administrators to reproduce protocol applications in the minutes.

271. University of California

I am responding: On behalf of an organization

Name:

Name of Organization: University of California

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

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UNIVERSITY OF CALIFORNIA

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OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
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Oakland, California 94607-5200

Submitted through: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

October 16, 2026

Office of The Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

RE: UC Comments in Response to NOT-OD-26-112, "Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards"

Dear Sir or Madam:

We write on behalf of the University of California (UC) with regard to the Request for Comment on the Draft National Institutes of Health Biosafety Policy for Research Involving Biohazards issued on August 19, 2026 (Draft NIH Biosafety Policy). The UC is comprised of ten campuses, six academic health centers, an Agriculture and Natural Resources division, 21 health professional schools, and three affiliated U.S. Department of Energy national laboratories.

UC stands at the forefront of cutting-edge research and technology development. As a system, UC receives approximately $7.5 billion annually of extramural awards to support research conducted throughout all UC locations. UC is awarded more NIH and National Science Foundation (NSF) funding than any other institution in the country.

While UC welcomes several aspects of the Draft NIH Biosafety Policy, including a simplified review structure and terminology, greater transparency through a public incident database, and the addition of delegated review, there are several concerns that need to be addressed before full implementation. As the Policy is refined, we encourage NIH to promote consistent interpretation across institutions and ensure that communication and review requirements do not unnecessarily delay research. Given the longstanding role of the NIH Guidelines for Recombinant and Synthetic Nucleic Acids in institutional biosafety programs, clear and practical requirements will be essential for successful implementation of the new Policy.

UC recognizes that the Policy is intended to be less prescriptive, however, it is too ambiguous and lacks detail for consistent application across institutions. NIH should provide examples as well as optional implementation tools and supplemental guidance documents that institutions may choose

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to use. In addition to the specific comments provided below, UC supports and endorses the comment letter submitted by Campus Safety, Health, and Environmental Management Association (CSHEMA) on October 12, 2026 in response to this request for comment.

1. Define and narrow policy scope to apply oversight proportionate to the risk.

Scope Ambiguity: The Policy requires significant clarification regarding its scope and applicability before it can be implemented consistently and effectively across institutions. As currently written, shown below, the scope is ambiguous about which activities fall under the Policy:

The NIH Biosafety Policy covers all biomedical research, in laboratory settings, involving biohazards.

For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:

1. *Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;*
2. *Cells, viruses, or organisms, other than plants, that have been genetically modified;*
3. *Toxins, prions, and other self-aggregating proteins; or*
4. *Cells or organisms, other than plants, containing 1, 2, or 3 above.*

It is unclear whether the Policy is intended to focus solely on research involving biological agents that pose a direct risk to human health, or whether it broadly applies to all biological materials and research activities, with the sole exclusion of plants. NIH should provide examples illustrating how the scope applies to common categories of research, including synthetic biology, computational or *in silico* design, plants, arthropods, animal pathogens, toxins, and non-infectious or non-replicating materials.

Risk-Proportionate Thresholds: If the intent is to include all biomedical research involving biological agents, the Policy would represent a substantial expansion of oversight into many research activities that are historically considered low risk. Expanding oversight would significantly increase administrative burden without a demonstrated improvement in biosafety outcomes. A limiting threshold should be added such that covered work must present a credible, scientifically plausible risk of causing disease in healthy adult humans under reasonably foreseeable laboratory exposure routes and quantities. Consideration should be given to reduce the scope of the Policy by removing oversight of toxins, self-aggregating proteins, genetically modified Risk Group 1 organisms, and other low risk activities that were exempt under the previous version of the NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules.

Non-Human Health Risks: If NIH intends the Policy to address risks beyond human health, it should establish a separate and clearly defined threshold for credible environmental,

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agricultural, ecological, or animal-health consequences. Those risks should not be incorporated into the Policy through undefined or open-ended references to "biohazards".

Applicability to Non-NIH Funded Research: Because this Policy functions as an institution-wide regulation, it may impose significant compliance obligations on non-NIH funded research. The Policy should either limit applicability to NIH-supported research, or define clear boundary conditions for affiliates, tenants, leased space, and core facilities.

2. Clarify and standardize definitions and terminology throughout the Policy.

The Policy contains numerous terms that are either undefined, inconsistently defined, or insufficiently detailed for reliable implementation across institutions. Given the Policy's flexible structure, NIH should provide resources explaining key terms that are likely to produce inconsistent institutional interpretations. These resources should include examples and, where appropriate, criteria for determining when an activity falls within or outside a defined category.

Undefined Terms: The Draft Policy contains numerous undefined terms, which is problematic because the lack of a definition is cause for inconsistent interpretation across institutions. Accordingly, the following terms must be defined in the final Policy: "authorized organizational representative," "biohazard, "biohazardous," "biological toxin protein," "biosafety officer," "GDMO," "primary cells that may be contaminated by adventitious agents," and "well-characterized cell lines." For clinical research, additional terms requiring definitions include "shedding," "replicating," "integrating," "higher risk manipulations," and "product."

Inconsistent Use: The term "biological agent" is used inconsistently throughout the Policy. For example, the definition describing biological agents as "bacterial, viruses, fungi, or parasites that cause human disease" does not encompass all biological agents addressed by the Policy, including "gene drive modified biological agent" and "RG1 wild-type biological agents." Because not all biological agents cause human disease, "human pathogenic agent" may be a more accurate term where the Policy specifically intends to refer to agents capable of causing human disease.

Definitions that Require Clarity: The definition of "toxin" is overbroad and, as written, does not accurately describe a toxin. Unlike other biological agents, toxins do not replicate and may be more appropriately considered analogous to chemical hazards. The definition should clarify the characteristics of toxins, such as toxicity (LD_{50} or LC_{50}) and if small molecule toxins are intended to be included. The definition of "laboratory research" should also be revised to encompass research activities and settings that may require biosafety oversight but do not neatly fit within a BSL/ABSL 1-4 designation. Examples include arthropod containment, clinical research activities, and research with plants expressing toxins that affect humans.

3. Broaden the reference framework for risk assessment and containment standards.

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Limitations of Reliance on the Biosafety in Microbiological and Biomedical Laboratories (BMBL): The Draft Policy relies heavily on the BMBL for agent-specific containment requirements. However, the BMBL does not provide Risk Group classification for agents and lags behind emerging or rapidly evolving research. Institutions have historically relied on the NIH Guidelines for Recombinant and Synthetic Nucleic Acids, World Health Organization, the Public Health Agency of Canada, or other recognized national and international authorities to assist in determining the agent Risk Group. The Policy should provide the risk-based rationale for prescribed minimum biosafety levels and clarify how its requirements apply outside conventional benchtop laboratories, including clinical, animal, large-scale, and other research settings where appropriate containment may depend on site-specific engineering, administrative, and procedural controls.

National Risk Group Classification and Institutional Authority: NIH should maintain an authoritative, regularly updated Risk Group classification resource, similar to the agent classification framework included in earlier versions of the NIH Guidelines for Recombinant and Synthetic Nucleic Acids. NIH should establish a defined process and frequency for reviewing and updating agent classifications and containment recommendations. NIH should establish nationally consistent Risk Group classifications, while institutions retain authority to determine appropriate biosafety level, containment requirements, and oversight based on local IBC risk assessments, available controls, and the specific research being conducted.

NIH should also clarify the relationship between Risk Group classification and Containment Levels. Risk Group classification generally describes the hazard associated with an agent or activity, while Containment Level describes the controls and containment measures appropriate for a particular operation. The final Policy or accompanying guidance should not treat these concepts as interchangeable. NIH may establish national minimum expectations or reference points, but the institutional IBC should retain the authority to assign or approve the appropriate containment level for a specific activity based on the institution’s risk assessment, available engineering and administrative controls, institutional risk acceptance, and applicable internal standards. Institutions should also be permitted to impose more stringent containment or oversight requirements when warranted by site-specific conditions.

NIH Review Process and Timelines: The Policy should clarify what constitutes an "initial request," when NIH approval is required, and whether determinations apply to individual experiments or more broadly to an agent or category of research. NIH determinations and their rationale should be publicly available and applicable across institutions when appropriate, reducing duplicative submissions and unnecessary delays. NIH should define what constitutes a "timely" review by establishing target turnaround times, completeness criteria, a process for additional information requests, and an expedited pathway for urgent public health research. NIH should provide decision trees, a searchable repository of prior determinations, and pre-authorized categories for well-characterized agents, attenuated strains, and replication-defective vectors to further reduce unnecessary case-by-case review.

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UC supports the proposed streamlined process under which an NIH-approved containment reduction is publicly posted and may subsequently be relied upon by other IBCs without separate NIH approval. NIH should clarify whether each determination applies to a particular agent, strain, construct, or activity; the information institutions must retain; the circumstances requiring renewed review; and the extent to which IBCs may impose more stringent controls based on site-specific conditions.

4. **Preserve Institutional Biosafety Committee (IBC) authority and institutional-based risk assessment.**

IBC as Primary Oversight Body: The proposed Policy should preserve the longstanding role of Institutional Biosafety Committees as the primary bodies responsible for conducting research-specific risk assessments and determining appropriate containment. Multiple provisions appear to shift decision-making authority from the institutions to NIH while simultaneously emphasizing risk-based oversight. Consistent with the Policy's focus on human health, IBC expertise requirements should be strengthened to include expertise in biosafety, public health, and infectious diseases. Animal research expertise should be included, as applicable, without specifying the animal model type, to allow institutions to evaluate the relevant expertise needed. The Policy should retain the requirement for a BSO for large-scale biological research.

Full Review versus Delegated Review Requirements: The Policy should clearly distinguish activities that require full IBC review from those eligible for delegated review. Requiring review of all genetically modified cells, viruses, or organisms could create substantial burden for routine low-risk research. This is particularly relevant for genetically modified arthropods and animals. The apparent inconsistency between delegated review for transgenic organisms at BSL-1/ABSL-1 and the BSL-2 minimum containment requirement for GDMOs should be resolved. NIH should provide a tiered decision framework, with examples of activities that may be handled through full IBC review, delegated review, or exemption. The framework should identify escalation triggers, while preserving institutional authority to impose additional review based on site-specific circumstances.

Expand Delegated Review Criteria: The defined delegated review criteria may be too narrow given the expanded scope, producing net added burden for low-risk work. These criteria should be expanded for routine low-risk research such as replication-incompetent or non-integrating vectors, reporter-only constructs, cell lines, primary materials, transgenic animals, low-risk genetically modified organisms, with clear criteria for when elevation to full IBC review is required. A full committee review of these research materials would be overly burdensome and would fall more in line with the delegated IBC review tasks based on risk.

Exemptions from the Policy: NIH should clearly explain how exemptions are intended to operate under the new Policy, including whether existing institutional practices may continue, whether exempt determinations require IBC review or documentation, and what circumstances

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require escalation to delegated or full IBC review. NIH should address transition expectations for exempt research activities that may not have been historically reviewed by the IBC.

NIH should distinguish between activities that are outside the scope of the Policy, activities that are exempt from formal IBC review but remain subject to institutional documentation or oversight, and activities eligible for delegated review. This distinction should be reflected in the Policy's definitions, decision tools, and implementation guidance.

Occupational Health and Safety Plan Clarification: Additional clarification is needed regarding the Occupational Health and Safety Plan (OHSP), including when such plan is required, the elements NIH expects institutions to maintain, and the scope of NIH oversight or authority in this area.

5. **Revise public disclosure requirements for Institutional Assurances, meeting minutes and incident reports that balance transparency with privacy, biosecurity and reporting integrity.**

Redaction and Security Standards: Public posting of IBC meeting minutes, incident reports, and Institutional Assurances without uniform standards for disclosure and redaction may create security, privacy, proprietary, and reputational risks and could discourage timely and complete reporting. The Policy states that "appropriate and allowable redactions" can be made. To promote consistency across institutions, NIH should establish and publish a standardized redaction framework that clearly identifies information that should be withheld, including sensitive facility or inventory information, security vulnerabilities, proprietary methods, titles, and personal identifiers. Public disclosure requirements should account for incidents involving ongoing investigations, litigation, privacy restrictions, or oversight by another federal or state agency. For BSL-3, BSL-4, GDMO, "other pertinent information," or other potentially security-sensitive research, NIH should not require public disclosure of information that could compromise broader federal biosecurity objectives, reveal protected intellectual property or proprietary information, or create material financial, competitive, privacy, or security harms. The Policy should clearly define the minimum information that must be publicly available and establish consistent standards for withholding or redacting protected information.

Incident Reporting Thresholds and Timeline: NIH should replace institution-by-institution public posting of all incident reports with a two-tier reporting framework. NIH-reportable and high-consequence incidents should be reported to NIH and summarized publicly using standardized redactions. Lower-risk incidents, near misses, and anomalies should be maintained through institutional systems and aggregated in a centralized, de-identified database. Further, NIH should establish clear reporting thresholds that distinguish events involving a credible exposure or release pathway from contained anomalies in which redundant controls remained effective. The Policy should clarify the relationship among incident reports, IBC meeting minutes, and Institutional Assurances, including how confidentiality, retention, and disclosure requirements apply when an incident involves multiple protocols or grant funding periods.

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Additional time beyond the 24-hour requirement or alternative disclosure procedures should be available for security-sensitive incidents or those subject to active investigation.

Centralized Incident Database: Given NIH's proposal to establish a centralized capability to aggregate, de-identify, and analyze biosafety incidents, near misses, and anomalies, NIH should consider using this mechanism to provide a centralized, anonymized public database rather than requiring institutions to publish individual reports on their website. This approach could provide meaningful transparency and opportunities for shared learning while preserving the culture of trust necessary for robust internal incident and near-miss reporting.

Continuity Mechanism: The Policy should include a continuity mechanism, such as an extension while an Institutional Assurance renewal is under NIH review, to ensure that administrative processing delays do not unnecessarily interrupt otherwise compliant research.

6. **Clarify containment and oversight standards for gene drive modified organisms and address environmental, agricultural, animal and arthropod risks more comprehensively.**

Oversight of Genetically Modified Plants: NIH should clarify whether another federal agency will have oversight authority for genetically modified plants and provide justification for their exclusion from this Policy. Genetically modified plants may express toxins, have the potential to contaminate native plant varieties through pollen or seed flow, and may impact associated arthropod communities or soil microbiota.

Arthropod Oversight and Containment Levels: While gene drives in animals, including arthropods, require increased containment levels under this Policy, similar requirements for plants have been removed from IBC oversight. The Policy should clarify if gene drive modified organisms that do not impact human health are within the scope of this policy. The requirement for research with gene drive modified organisms to be conducted at a minimum of BSL-2 containment is a poor fit for genetically modified insects such as mosquitoes, flies, or other arthropods, as the biosafety level terminology primarily focuses on infectious-agent risk. For many gene-drive or genetically modified arthropods, the principal hazard is environmental escape and establishment, not infection of laboratory personnel. As such, the appropriate terminology would be arthropod containment levels (ACL). The Policy should distinguish between human health biocontainment and environmental containment of genetically modified organisms.

Environmental, Agricultural, and Animal Health Risk: More broadly, environmental risk and consideration is captured in multiple sections of the Policy, but only human health is noted in the scope of this Policy. The Policy should clarify if environmental, agricultural, and animal health risk should be considered under the scope of this Policy. Any environmental, agricultural, ecological, or animal-health risks included within the Policy should be governed by the separate threshold described in Section 1 and should not expand the Policy’s scope through open-ended interpretation of “biohazard”.

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7. Reduce administrative burden and eliminate regulatory redundancy.

Extend Implementation Timeline: The implementation timeline should be extended from "6 months from publication of final Policy" to a minimum of 12 months to allow institutions sufficient time to develop and validate systems necessary to comply with the new Policy. NIH should clarify how the proposed institutional biosafety assurance is intended to complement existing compliance certifications associated with NIH funding to ensure the process avoids duplicative administrative requirements. Each assurance requirement should be revised to express each statement as a complete, clearly defined institutional responsibility or submission element. Model templates and electronic resources should be made available ahead of the Policy effective date, including risk assessment tools, delegated review templates, incident reporting template, redaction guidelines, and public meeting minute formats.

Records Retention: Records-retention requirements should be specific to IBC oversight rather than directly tied to award financial-record retention periods. IBC oversight is based on active institutional research and does not necessarily align with grant submission or financial-reporting cycles. Accordingly, the Policy should define the categories of records subject to the retention requirement and distinguish institutional IBC records from grant records. IBC protocols are often living documents that evolve with active research and institutional controls and may not correspond directly to the scope of an individual grant proposal.

IBC Submission Timeline: Requiring a *de novo* IBC registration submission every 3 years can present a significant administrative burden on both the Principal Investigator and the IBC. NIH should allow institutions to establish periodic review intervals based on the nature and the risk level of the research.

Meeting Minutes Documentation and Public Posting: Public-posting requirements should be limited to information necessary to promote meaningful transparency and accountability. The requirement to post approved minutes immediately following approval, or by the next convened meeting, should be modified to provide institutions reasonable flexibility based on meeting frequency and administrative capacity.

Meeting Minutes and Incident Report Templates: Mandatory NIH templates for meeting minutes and incident reports may be overly prescriptive for institutions with established electronic systems and may increase administrative burden without improving safety outcomes. NIH should consider permitting substantially equivalent formats, including exports from institutional electronic systems, provided all required data elements are captured. NIH should publish a machine-readable list of required fields to standardize content while minimizing duplicative work. Additionally, NIH should consider removing training information from the meeting minutes template. Personnel training records are dynamic in nature and may contain personnel-identifying information that institutions would otherwise need to redact prior to making records available to the public. Training documentation is more appropriately maintained through separate institutional tracking mechanisms.

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Standardized IBC Training: NIH should create and publish standardized IBC member training to outline the roles and responsibilities of IBC membership and include information about the review process. This would ensure that local IBCs are analyzing and assessing research activities with consistency instead of relying on third party or institution-created training for their IBC members.

Coordination with Existing Federal Oversight: Additional clarification is needed regarding the relationship between this Policy and other existing federal oversight. Several areas appear to overlap with established requirements administered by Occupational Safety and Health Administration (OSHA), Federal Select Agent Program (FSAP), Food and Drug Administration (FDA), Animal and Plant Health Inspection Service (APHIS), and the recently issued July 2016 United States Government Policy for Stopping High-Risk Life Sciences Research. The Policy should clearly identify which agency has primary oversight responsibility when multiple regulatory requirements apply and explain how overlapping requirements will be coordinated to avoid duplication or conflicting determinations. NIH should define which specific requirements outlined in the Policy are applicable when research may fall under the purview of multiple agencies or federal policies.

8. **Establish a clear biosafety oversight framework for clinical research.**

IBC Role in Clinical Research: The Policy does not adequately define the IBC's role in overseeing clinical research. IBC oversight of clinical research should complement, rather than duplicate, other federally required review and applicable human-subject protections. Where FDA and other regulatory processes already address product safety, shedding, or related risks, the Policy should clearly define the specific biosafety issues that remain within IBC oversight and establish clear endpoints for that oversight, such as last administration of an investigational product and a defined, evidence-based shedding monitoring window. This gap can create duplicative oversight, administrative confusion, and unnecessary delays for clinical research programs. The clinical research provisions should be reconciled with the 21st Century Cures Act, the Common Rule under 45 CFR 46, and existing FDA oversight frameworks.

Clinical Definitions and Terminology: As noted in our definitional comments, the absence of definitions for "shedding," "replicating," "integrating," "higher risk manipulations," and "product" creates significant challenges for institutions to apply effective clinical biosafety oversight.

Hierarchy of Controls and Tiered Risk Management: The Policy's risk assessment considerations for clinical research should take a layered approach to safety and focus on the hierarchy of controls. While the Policy acknowledges that clinical laboratories do not use traditional biosafety levels, the only risk mitigation guidance provided for clinical personnel is the use of universal precautions. This significantly understates the appropriate approach to clinical biosafety. Standard precautions should serve as the established baseline, with transmission-based precautions implemented based on the hazard characteristics and routes of

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transmission specific to the investigational product or procedure. The Policy should reflect a tiered model of risk management.

9. Provide guidance for synthetic biology and artificial-intelligence assisted research.

Emerging Technology Oversight Gap: The rapid advancement of synthetic biology and artificial intelligence-assisted research design represents a growing category of biosafety concern that the Policy does not address. Both technologies have the capacity to substantially accelerate research workflows, lower barriers to the design and synthesis of novel biological agents and produce outcomes that existing oversight frameworks were not designed to evaluate. NIH should provide implementation guidance and institutional review tools for these areas, either in the final Policy or in accompanying guidance.

Synthetic Biology: With respect to synthetic biology, the Policy should provide guidance on the oversight of research involving the *de novo* synthesis of genetic sequences, the creation of novel biological constructs without natural counterparts, and the application of standardized biological parts in ways that may confer new or enhanced properties on organisms or agents. NIH should provide criteria and examples identifying which categories of synthetic biology work require IBC review, delegated review, or no additional biosafety review.

Artificial Intelligence and Large Language Model-Assisted Biological Design: With respect to artificial intelligence (AI) and large language model-assisted biological design, the Policy should establish review triggers and minimum institutional safeguards applicable when AI tools are used to propose, optimize, or select biological designs tied to high-consequence properties, including enhanced transmissibility, expanded host range, immune evasion, antimicrobial resistance, environmental stability, or increased toxicity. These safeguards should be narrowly and precisely defined so as not to impede general computational research, bioinformatics, or routine AI-assisted data analysis, while ensuring that AI-facilitated pathways toward potentially dangerous agent characteristics are subject to appropriate institutional and federal oversight.

10. Required Guidance Documents and Implementation Resources

To support consistent implementation while preserving institutional flexibility, NIH should make the following guidance documents, templates, decision tools, and reference resources available before the effective date of the final Policy.

- Examples of research activities and determinations to assess if the work falls within the scope of the Policy
- Guidance confirming institutional IBC authority to assign or approve containment and oversight based on research-specific risk assessment, institutional risk acceptance, available controls, and internal standards
- Risk group classifications
- Template to request NIH determination for risk group assessment and biosafety level reduction

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- Guidance on reliance upon posted NIH containment-reduction determinations, including the scope and applicability of each determination, criteria for when a new NIH request is required, and documentation and recordkeeping requirements for IBCs relying on a prior determination
- Searchable repository of prior NIH determinations on Risk Group classification and Biosafety Level or containment reduction
- Incident report template
- Incident reporting decision tree on what is required to be submitted to NIH and publicly posted
- Guidance on incident-reporting timelines, redactions, active investigations, and alternative disclosure procedures
- Machine-readable list of required fields for public meeting minutes
- Risk assessment template with references beyond the BMBL
- Guidance on environmental, agricultural, ecological, animal-health, and arthropod risks
- Decision tree distinguishing activities outside the scope of the Policy, activities exempt from formal IBC review but subject to institutional documentation or oversight, activities eligible for delegated review, and activities requiring full IBC review.
- Delegated review template
- Standardized redaction reference
- Standardized IBC member training
- Occupational health and safety plan template
- AI and LLM research examples with determinations if they are within the scope of Policy
- Synthetic biology risk assessment template

Thank you for the opportunity to comment. We look forward to continued engagement on this important Policy.

Sincerely,

[redacted]
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Kevin Confetti
Associate Vice President & Chief Risk Officer
Office of Risk Services
University of California Office of the President

[redacted]

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis & Coordination
University of California Office of the President

272. Battelle Memorial Institute

I am responding: On behalf of an organization

Name:

Name of Organization: Battelle Memorial Institute

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: PURPOSE
Because the NIH is extending their policy to vast swathes of non-NIH funded biological science research, development, testing and evaluation funded by the U.S. Government, the NIH should also commensurately reflect the broader U.S. Government biological science drivers in their purpose statement. Hence, we recommend that the NIH include the following sentence in their purpose statement. The first paragraph under the Purpose heading is recommended to be modified as follows: "As the world's largest public funder of biomedical research, NIH is committed to ensuring that gold-standard science is conducted under gold-standard biosafety conditions…"

Insert: The NIH is also committed to preserving and advancing the United States' research and development advantage on the global stage by strengthening both basic and applied biological science process and practice guidance, while maintaining a robust biosecurity and biological defense posture.

"…The purpose of the NIH Biosafety Policy for Research Involving Biohazards (the Policy) is to achieve this goal by setting forth requirements for federal and local institutional oversight of biomedical research involving biohazards, and to help ensure the safe, responsible, effective, and secure conduct of such research." We recommend that the NIH also leverage the National Biosafety Data and Safety Analysis Center (NBDSAC) function to reduce the new policy-imposed vulnerabilities that the draft NIH Biosafety Policy generates, if implemented as written.

The NIH is also inadvertently opening a large security gap with this draft language. The draft policy generates a new personally identifying information (PII) vulnerability by linking discoverable personal names with biological science, and more seriously biological defense, scope. It is strongly recommended that the NIH consult with senior U.S. Federal law enforcement stake holders to more fully assess the policy-imposed vulnerabilities that would be generated if this guidance document is implemented as written.

NON-NIH FUNDED RESEARCH

The draft would apply to covered non-NIH-funded research conducted at an institution receiving NIH funding. This would extend NIH requirements to research sponsored by other federal agencies and private entities, including work that may be subject to sponsor confidentiality, proprietary-information, security, or contractual restrictions.
• Many CRO client studies involve proprietary projects of short duration protected by confidentiality agreements.
• Requiring public disclosure of this work can violate client contracts and jeopardize intellectual property (IP).

Mandatory public disclosure imposes unnecessary burdens and discourages sponsors from using US-based CROs, weakening the US biological science enterprise.

The NIH wisely added wording at the end of Section II. Scope stating that "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." We recommend adding clarity to Section III-B. IBC Functions so that the second sub-bullet under the first main bullet reads: "When possible and consistent with protection of privacy, proprietary interests, and national security concerns…
INSERT: and within the constraints of other federal agency oversight referenced in Section II. Scope,"

• NIH should limit mandatory applicability to NIH-supported research and encourage voluntary adoption for other research from other funding sources.
• If NIH retains institution-wide applicability, NIH should create a defined process for work subject to other federal oversight or sponsor-imposed disclosure restrictions and clarify how such work can comply without public release of restricted information. This process should explicitly safeguard client identities, proprietary methods, Controlled Unclassified Information (CUI), and IP so that CROs can maintain a diverse client base without jeopardizing business relationships or breaching contractual obligations.

OTHER FEDERAL OVERSIGHT AND REQUIRED CLEARANCES
The provision allowing research to proceed under another federal agency's oversight is not sufficiently specific. The draft does not identify which agencies or programs qualify, what approvals or clearances are required, or which NIH requirements continue to apply.
• NIH should identify qualifying agencies and programs, including the Federal Select Agent Program where applicable, and define the approvals or clearances required.
• NIH should clarify which agency has priority for compliance determinations and how duplicative or conflicting requirements will be resolved, particularly where Federal Select Agent Program (FSAP) security and inventory rules already govern the work and public disclosure would conflict with those rules. We recommend that the FSAP rules have priority over NIH Biosafety Policy.
• NIH should clarify priority when multiple qualifying agencies are applicable.
• NIH should clarify what approvals or clearances are required to follow other agency oversight and how those are obtained.

REFER TO ATTACHMENT
In addition to these comments, please refer to the submitted attachment for a more detailed discussion

of the concerns and recommended actions for NIH consideration. For clarity, these associated concerns are as follows:

ITEM 1: PUBLIC DISCLOSURE of program details through the BIOSAFETY ASSURANCE
DRAFT REFERENCE: Section III-A (Assurance submissions: weblinks "to the maximum extent possible" to procedures, a continuously updated IBC roster, minutes, processes for how biosafety risks are managed, incident reports, training synopses; whether the institution conducts BSL-3/4 research).

CONCERN: The Assurance would direct the public to a consolidated profile of each institution, including where high-containment work is conducted. This information supports transparency, but it is equally useful to those who wish to target personnel, disrupt operations, or gain inside knowledge of how a program functions.

Procedures and incident reports are written for a technical audience and do include the context needed to understand them. However, the general public is unlikely to have the specialized biosafety knowledge to interpret that context accurately, so these documents are likely to be misread or misinterpreted. Continuous updating and long retention increase both risks. The draft policy contains no express authority to withhold security-sensitive material from the public weblinks.

REQUESTED ACTION
• Remove the expectation that the Assurance submissions link to public postings of procedures, processes for how biosafety risks are managed, rosters, minutes, training synopses and incident reports.
• Allow institutions to provide this information to NIH confidentially, with public disclosure limited to a high-level institutional attestation of compliance.
• Do not require public identification of BSL-3/4 or GDMO capability at the institution level.
• State expressly that institutions may withhold security-sensitive information, and require that NIH protect submitted Assurances from public release to the extent permitted by law.
• Allow institutions to submit the same information already submitted to other federal regulatory programs (e.g., the Federal Select Agent Program) rather than creating duplicate or conflicting information.

ITEM 3: “INCIDENT” AND “SIGNIFICANT RISK TO HUMAN HEALTH” ARE UNDEFINED, AND “ANY INCIDENT” AT BSL-3/ABSL-3 AND BSL-4/ABSL-4 IS OPEN-ENDED
DRAFT REFERENCE: Section III-B, IBC Functions (reportable incidents "pose a significant risk to human health"; "any incident" at BSL-3/ABSL-3 or BSL-4/ABSL-4; 24-hour notification to NIH)

CONCERN: Section III-B states that reportable incidents are those that "pose a significant risk to human health." The draft policy defines neither "incident" nor "significant risk to human health," and it gives no objective test for either. The list then covers "any incident" at BSL-3/ABSL-3 and BSL-4/ABSL-4. The list is introduced with "including," but "any" combined with an undefined term can reasonably be read to capture every event at those levels, regardless of risk. The word "any" also contradicts the stated "significant risk" threshold. The likely results are subjective and inconsistent determinations across institutions, over-reporting, and a 24-hour clock applied to events that do not pose a significant risk to human health.

REQUESTED ACTION
• Define "incident" in the draft policy with objective criteria.
• Define "significant risk to human health" and use it as the single threshold for every reportable category.
• Replace "any incident" at BSL-3/ABSL-3 and BSL-4/ABSL-4 with a closed, enumerated list of reportable event types. Examples are confirmed or potential laboratory-acquired infection, overt exposure (as defined by NIH), and loss of containment with potential for exposure.
• Provide decision criteria and examples for events below the threshold. State that these are documented and handled internally under IBC oversight rather than reported to NIH or publicly posted.

ITEM 4: “BIOLOGICAL AGENT INVENTORY...”
DRAFT REFERENCE: Section III-B, IBC Functions (BSL-3/ABSL-3 and BSL-4/ABSL-4 incident list)

CONCERN: The phrase "may have public health consequences" is speculative and has no objective test, because almost any inventory or security event could arguably meet it. Inventory and security events involving select agents and toxins are already governed by the Federal Select Agent Program (42 CFR Part 73; 7 CFR Part 331; 9 CFR Part 121). A parallel 24-hour NIH report, followed by public posting, duplicates that oversight. It also publicizes security information that is normally protected and could be exploited by malicious actors.

REQUESTED ACTION:
• Exclude agents regulated under the Federal Select Agent Program from this category, and defer to that program and other applicable security regimes.
• If any version is retained, replace "may have public health consequences" with an objective standard.
• State explicitly that inventory, security and access-control information is excluded from any public posting.

ITEM 7: APPLICATION OF THE DRAFT POLICY TO NON-NIH FUNDED RESEARCH AT ANY INSTITUTION RECEIVING ANY FUNDING
DRAFT REFERENCE: Section II, Scope ("This Policy is also applicable to non-NIH funded research that is conducted on or after [effective date] at an institution that receives any NIH funding"; the Scope also applies "regardless of NIH funding level or funding mechanism"); Compliance and Enforcement (institutions "shall ensure that any research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with this Policy"); General Definitions, "Biomedical research" (includes "non-NIH funded research that is conducted at an institution that receives any NIH funding"); Section III-A (no research subject to the draft policy may be conducted until NIH approves the institution's Biosafety Assurance)

CONCERN:
• Overreach. The draft policy already defines "NIH-supported research" as all research funded in whole or in part by NIH. It then extends the draft policy to every other research program at the institution. A single NIH award of any size, through any mechanism, would pull in the institution's entire portfolio,

including work funded by other federal agencies and private clients. Institutions that draw funding from many sources are affected most and are disproportionately impacted. The connection between receipt of NIH funding for one project and regulation of unrelated research activities elsewhere within the institution is not clearly articulated.

• Contractors, collaborators and shared facilities. The draft policy also, as written, does not address how obligations apply to contractors, subcontractors, collaborators, partnerships, or shared facilities. There may be conflicting oversight obligations when only some participating organizations receive NIH funding.

• Existing oversight. Much of this work is already overseen by its own sponsors and regulators, especially at the federal level. These sponsors often require comparable biosafety documentation, reviews and incident reporting. Applying NIH requirements on top creates duplicate review and reporting, and it can produce conflicting findings and timelines. The deference language in Section II refers only to "another federal agency," does not define the "approvals or other applicable clearances" required, and does not address private sponsors.

• Financial burden. Institutions would have to submit and maintain an Assurance, put additional protocols through IBC review, complete incident reports, and publicly post information for programs that NIH does not fund. The notice materials do not include a cost estimate for this expansion, and the costs would fall on institutions and, through them, on non-NIH sponsors. Low-risk non-NIH-funded projects may become subject to the same administrative burdens as activities that present substantially greater biosafety risk.

• Delay. The draft policy bars all covered research until NIH approves the Assurance, and it sets no review deadline for NIH. Because the draft policy reaches non-NIH work, an NIH delay could stall sponsor programs that have fixed contract schedules and deliverables, even though NIH is not funding or directing the work.

• Sponsor restrictions. Public posting and disclosure requirements can conflict with confidentiality, proprietary-information, controlled unclassified information, export-control and security terms in sponsor agreements. An institution cannot unilaterally breach those terms, and the draft policy provides no mechanism to reconcile them.

• Classified work. The draft policy does not address government-classified research. Classified programs cannot be disclosed in an Assurance, in IBC minutes or incident reports, or on a public website. The existence of such work may itself be restricted. The draft policy's redaction language covers information that would "directly compromise institutional or national security," but only for the public posting of reports. It does not address the Assurance, IBC review, NIH reporting, or the personnel and clearances needed to review such material. Without accommodation, institutions with classified programs cannot show compliance without violating their security obligations.

• Enforcement exposure on non-NIH work under undefined standards. The draft policy states that failure to comply "may provide a basis for enforcement actions, including, but not limited to, additional special terms and conditions, or termination," and that enforcement "may affect future funding decisions for the recipient institution." Because the draft policy extends to non-NIH-funded work, an institution's NIH funding could be put at risk over research that NIH does not fund. The standards against which compliance would be judged are not yet defined. Examples include what "pose[s] a significant risk to human health"; what counts as an "incident" or as "any compliance violations"; what "a timely manner" means (the same draft policy that leaves NIH's response time undefined); what "other pertinent information" must be provided; and what redactions are "appropriate and allowable." Institutions cannot reliably demonstrate compliance with terms they must interpret on their own, and two

institutions could reach different, equally reasonable readings. The phrase "including, but not limited to" also leaves the range of possible enforcement actions open. Enforcement consequences this significant should rest on requirements that are clear, objective and known in advance.
• Competitive impact. The draft policy could create an uneven competitive landscape. Institutions that receive NIH funding would incur additional oversight, reporting, Assurance, and public disclosure obligations across their research portfolio, while institutions conducting comparable non-NIH-funded work without NIH funding would not. This may discourage participation in NIH-funded research and create incentives to separate research activities among affiliated entities.
• Commercial sponsor impact. Commercial sponsors may be unwilling to place proprietary research at institutions subject to mandatory public posting or NIH oversight on non-NIH-funded work. This could reduce research opportunities and increase costs for institutions and sponsors.

REQUESTED ACTION:
• Limit the draft policy to NIH-supported research as the draft policy already defines it. Delete the non-NIH-funded sentence in Section II, the "irrespective of the source of funding" language in Compliance and Enforcement, and the non-NIH clause in the "Biomedical research" definition.
• Continue to encourage voluntary adoption for other research, as the Voluntary Compliance section already provides.
• If NIH retains institution-wide application, require that it apply at the project or facility level, not through one institution-wide gate. Exempt research already overseen by another federal agency or by sponsor-required biosafety oversight from NIH review, incident reporting and public posting, and accept the other oversight body's documentation as meeting NIH's requirement.
• If NIH retains institution-wide application, exempt non-NIH-funded projects already underway before the effective date.
• Add an express provision for classified research. It should state that classified work is overseen under applicable national security requirements. It should also say that nothing in the draft policy requires disclosure of classified information, including the existence of the work, in an Assurance, in IBC records, or in any report to NIH or the public. Provide a compliance pathway that does not depend on disclosure.
• Provide an exemption or a defined process for sponsor-restricted work (proprietary, controlled unclassified, export-controlled or contractually confidential), with no public posting.
• Clarify whether the draft policy applies to contractors, subcontractors, and shared facilities.
• Do not gate research that NIH does not fund on NIH approval of the Assurance. If any non-NIH work stays in scope, set fixed NIH review deadlines and allow work to continue under existing sponsor and IBC oversight while review is pending.
• Publish a cost and burden analysis specifically for the expansion to non-NIH-funded research.
• Define the terms listed above in the draft policy before any enforcement authority applies, and tie each enforcement action to a specific, enumerated requirement.
• Limit enforcement actions affecting NIH funding to NIH-supported research. Do not link NIH funding decisions to compliance on non-NIH-funded work.
• Establish a graduated, documented enforcement process: written notice of the specific requirement allegedly not met, a reasonable opportunity to respond and correct, and an appeal path before any special terms, termination or funding consequence.
• Provide a good-faith compliance provision. Institutions that make a reasonable, documented interpretation of an undefined term would not face enforcement while NIH is still issuing

implementation guidance.
• Replace "including, but not limited to" with a defined list of possible enforcement actions.

ITEM 8: REPORTING OF “POTENTIAL RELEASES” FROM FACILITY OR EQUIPMENT FAILURES “EVEN WHEN REDUNDANT SYSTEMS WERE FUNCTIONING PROPERLY”
DRAFT REFERENCE: Section III-B, IBC Functions (reportable incidents at BSL-3/ABSL-3 or BSL-4/ABSL-4: "potential releases involving facility and/or equipment failures, even when redundant systems were functioning properly, to address the possibility of risk to personnel and the community and prevent future occurrences"); Section III-C (voluntary, confidential near-miss reporting to the National Biosafety Data and Safety Analysis Center)

CONCERN:
• Circular trigger. Redundant systems exist to prevent releases. When they function properly, no release occurs. The clause nevertheless requires a report of a "potential release," so the trigger depends on something that did not happen. The draft policy does not define "potential release," so institutions cannot tell what counts. Requiring a report when backup systems perform exactly as designed treats successful risk mitigation as evidence of a reportable incident rather than a demonstration that the
• containment system functioned properly. In addition, public reporting of events in which containment was never lost may create the appearance of a biosafety failure where none occurred.
• Inconsistent with the "significant risk" threshold. Section III-B limits reportable incidents to those that "pose a significant risk to human health." A failure that a redundant system contained does not meet that threshold, and the draft policy does not reconcile the two.
• Undefined scope. "Facility and/or equipment failures" has no limits. Without a definition, a wide range of routine faults and maintenance events could become reportable. That would drive over-reporting, inconsistent determinations across institutions, and a heavy burden of review, reporting and public posting. A high volume of low-risk reports could divert attention from events involving actual exposures, releases, or containment failures.
• Disincentive to good design and candid reporting. Treating a successful backup as a reportable event discourages institutions from recording and discussing equipment faults openly. That works against NIH's stated aim of learning from near-misses.
• Inconsistent with the voluntary near-miss framework. The draft encourages voluntary, confidential reporting of near-misses and secondary failures to the National Biosafety Data and Safety Analysis Center, and it says NIH will not use that data for enforcement unless there was an environmental release or lab acquired infection. This clause requires essentially the same kind of event to be reported to NIH, and posted publicly, under the mandatory process.
• Overlap with existing oversight. Facility and equipment performance is already governed by existing biosafety, facility-maintenance and, where applicable, Federal Select Agent Program requirements. The draft does not say how this reporting relates to them.

REQUESTED ACTION:
• Delete "even when redundant systems were functioning properly." Events in which secondary or redundant controls performed as designed should not be reportable to NIH.
• Limit this category to equipment or facility failures that result in a loss of containment, an actual

release, or an exposure, or that create a documented potential for exposure that safeguards did not prevent. Define "potential release" with objective criteria.
• Handle failures in which redundant systems held as internal events, reviewed by the IBC and documented locally, as the draft already does for lower-risk incidents that "must be reported to and addressed by the IBC" but not NIH.
• Direct near-miss and secondary-failure information to the voluntary, confidential framework in Section III-C, with the protections stated there. Do not make it a mandatory, publicly posted report.
Define "facility and/or equipment failure" using objective, risk-based criteria such as loss of primary containment, loss of negative pressure beyond established limits, failure of decontamination systems, or failure resulting in actual exposure or release. Align any retained reporting with existing federal requirements, so one event does not trigger parallel reports.

ITEM 9: RECORDS RETENTION AND DURATION OF PUBLIC AVAILABILITY
DRAFT REFERENCE: Section III-A (records retention "in accordance with Section 8.4.2 of the NIH GPS … 2 CFR 200.334," and "IBC meeting minutes and incident reports must be publicly posted for a minimum of five years"; incident reports and minutes containing award-related records "must be made available to the public during this time if requested")

CONCERN:
• The draft policy ties records retention to the federal baseline of three years under 2 CFR 200.334 and NIH GPS 8.4.2, then sets a separate five-year public posting requirement. The two are different obligations, and the draft policy gives no safety rationale for the longer public period.
• 2 CFR 200.334 provides that Federal agencies "may not impose any other record retention requirements" except for specified circumstances. The draft policy does not identify which exception supports a five-year requirement.
• The draft policy does not say when the five years begin (posting date, meeting or incident date, or award closeout). Incident reports can span multiple protocols at different stages of the grant cycle, so institutions cannot determine when posting may end.
• The draft policy uses both "publicly posted" and "made available to the public … if requested." It does not say which applies to which records, or what happens when a record is only partly award-related.
• A longer public window increases the aggregation and security risks as well as hosting, review and redaction costs. It also prolongs the risk of misinterpretation by non-expert audiences. NIH already has access to retained records for as long as they are kept, so extended public posting is not needed for NIH oversight.
• For research that NIH does not fund, no federal award exists, so the retention baseline does not apply, yet the five-year public requirement would.
• The draft policy does not address whether corrected reports, amended findings, or updated corrective actions replace prior versions, nor does it explain which versions remain publicly available. Retaining outdated information for extended periods could create inaccurate public record, especially as biosafety practices and facility capabilities change over time.

REQUESTED ACTION:
• Align any public availability period with the existing three-year baseline, or remove the fixed minimum, and keep records for NIH access under existing retention rules.

• If NIH retains a longer public period, state the safety rationale and the legal basis, including which provision of 2 CFR 200.334 permits it.
• Define when the period starts and ends, and how it applies to records spanning multiple protocols or awards.
• Clarify which records must be continuously posted and which need only be provided on request, and permit removal after the period ends.
• Clarify when and how records are updated throughout the reporting process.
• Exempt non-NIH-funded research from the public availability requirement.

ITEM 10: DEFINITION OF “BIOMEDICAL RESEARCH” AS RESEARCH “WITHIN THE MISSION OF THE NIH
DRAFT REFERENCE: General Definitions, "Biomedical research" ("Research on a topic that is within the mission of the NIH," including non-NIH-funded research conducted at an institution that receives NIH funding); Section II, Scope. The draft policy repeatedly conditions applicability on "research," but does not provide a general definition of "research" itself, and the separate definition of "laboratory research" addresses only where the work occurs.

CONCERN: For institutions that conduct multidisciplinary research, these provisions create uncertainty regarding independently sponsored defense, commercial, veterinary, environmental, product-development, validation, quality-control, surveillance, and similar activities. Applicability also turns on "known or potential risk to human health," which the draft policy does not define, so it is unclear how these activities are treated where human health is not the focus of the work.

Because coverage determines whether an Assurance, IBC review, incident reporting and public posting apply, and because enforcement can affect NIH funding, institutions need to know in advance which activities are covered. The same definition is also the basis for extending the draft policy to non-NIH-funded research.

REQUESTED ACTION
• Provide objective criteria and representative examples for determining when independently sponsored work is sufficiently within the NIH mission to constitute covered biomedical research.
• Define "research" for policy applicability and distinguish it from operational testing, validation, quality control, manufacturing support, diagnostics, training, and other related biological activities.
• Establish a formal process for institutions to request written applicability or scope determinations for ambiguous projects and activities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): ADMINISTRATIVE AND RESOURCE BURDEN
The expanded scope and review responsibilities would require additional biosafety personnel, compliance support, and information-technology infrastructure. The draft does not provide sufficient detail for institutions to estimate or plan for these responsibilities. CROs face higher relative impact because they manage large numbers of short-duration client studies rather than long academic grants (each new or amended protocol still triggers a review process and client-driven changes frequently occur).
• NIH should provide clear implementation expectations, supporting tools, and a phased transition that accounts for institutional staffing and system needs.

• NIH should establish proportionate review and documentation pathways so that research eligible for delegated review is not subject to the same risk-assessment narratives, meeting-minute detail, renewal requirements, and administrative documentation as research requiring full IBC review. An abbreviated record should document the research category, principal hazards, containment, material safeguards, reviewer determination, and approval conditions, while detailed risk-assessment and deliberative records should be reserved for higher-risk or uncertain research requiring convened IBC review.
• NIH, similarly, should provide a pathway for repetitive research and expedited approvals as described in the bullet above.

INFORMATION REQUIRED FOR NIH DETERMINATIONS
The draft uses open-ended language such as 'other pertinent information' in connection with institutional Assurances and petitions to NIH. This prevents institutions and committees from knowing in advance what information NIH will require.
• NIH should publish complete submission elements and objective review criteria for Biosafety Assurances and containment-determination requests.
• NIH should clearly define the limited circumstances in which additional information may be requested.

In addition to these comments, please refer to the submitted attachment for a more detailed discussion of the concerns and recommended actions for NIH consideration. For clarity, these associated concerns are as follows:

ITEM 11: RELIANCE ON OTHER FEDERAL OVERSIGHT, INCLUDING THE FEDERAL SELECT AGENT PROGRAM
DRAFT REFERENCE: Section II, Scope states, "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." Section V-A separately recognizes that the Federal Select Agent Program oversees the possession, use, and transfer of Select Agents and Toxins and states, "All entities must follow the requirements laid out in the Select Agent Regulations."

CONCERN: Although Section V-A names the Federal Select Agent Program, the draft policy does not say whether it is a qualifying program under Section II, what approvals or clearances are required, whether other federal oversight replaces or supplements NIH requirements, or which NIH requirements continue to apply.

REQUESTED ACTION:
• Identify qualifying agencies and programs, including the Federal Select Agent Program, and define the approvals or clearances required.
• Establish a formal reliance or equivalency framework that identifies which NIH requirements are satisfied by another federal oversight program and how duplicative or conflicting requirements will be resolved.
• State whether work under another federal agency's oversight remains subject to NIH incident reporting, public posting and IBC review.

ITEM 12: THREE-YEAR DE NOVO APPROVAL REQUIREMENT
DRAFT REFERENCE: Section III-B (IBC Functions) requires the IBC to periodically review approved research and states that approval may not exceed three years, at which time a de novo registration submission and review is required. Changes that may affect the original biosafety assessment must be reviewed before implementation.

CONCERN: The draft policy does not define the frequency, scope, or documentation for periodic review. Requiring a complete de novo submission every three years for unchanged, compliant, lower-risk research may divert resources from higher-risk oversight without a corresponding improvement in risk control.

REQUESTED ACTION:
• Define periodic-review expectations based on risk, compliance history, complexity, and whether material changes have occurred.
• Permit streamlined renewal or administrative continuation for unchanged, compliant research and reserve full de novo review for material changes, elevated-risk work, significant incidents, or compliance concerns.

ITEM 24: CLARIFY THAT BSO RESPONSIBILITIES MAY BE FULFILLED THROUGH OVERSIGHT OF QUALIFIED INSTITUTIONAL PROGRAMS AND PERSONNEL
DRAFT REFERENCE: Section III-B, Biosafety Officer (BSO) Requirements and Duties

CONCERN: Section III-B is written as a single BSO personally responsible for conducting inspections, investigating incidents, and performing other operational functions. The draft policy does not recognize that these activities are often carried out by a multidisciplinary team or institutional program operating under the direct oversight of the BSO.
Requested action:
• Clarify that the BSO is responsible for the oversight, coordination, and effectiveness of these functions and that inspections, investigations, assessments, and related activities may be conducted by appropriately qualified personnel operating under the BSO's authority.
• Include the following language: "The BSO's duties may be carried out directly by the BSO or through the oversight, coordination, and review of appropriately qualified institutional personnel operating under the authority of the BSO."

3. Continued utility of Risk Groups: The draft relies on Risk Groups but omits the agent classification lists contained in the current NIH framework. Institutions need an accessible and stable classification resource to support consistent risk assessment and review.
• NIH should continue to provide the Risk Group classification system as part of the policy or a clearly controlled implementation resource.
• NIH should explain how updates to Risk Group classifications will be communicated and controlled so institutions can apply them consistently.

In addition to these comments, please refer to the submitted attachment for a more detailed discussion of the concerns and recommended actions for NIH consideration. For clarity, these associated concerns

are as follows:

ITEM 25: CLARIFY AUTHORITY AND RESPONSIBILITIES FOR BIOCONTAINMENT DETERMINATIONS
DRAFT REFERENCE: Section III-B, IBC Functions (independent risk assessment of required biocontainment levels and notification of the required biocontainment level); Section III-C, Responsibilities of the PI (initial risk assessment and selection of biocontainment levels).

CONCERN: The draft policy assigns containment-related risk assessment responsibilities to both the PI and the IBC but does not clearly identify who is responsible for proposing, evaluating, and approving the final biocontainment level. The requirement for both an initial PI risk assessment and an independent IBC risk assessment could be interpreted as requiring multiple independent evaluations of the same hazards without clarifying how disagreements should be resolved.

REQUESTED ACTION:
• Clarify that the PI is responsible for conducting the initial risk assessment and proposing the appropriate containment level and risk mitigation strategy.
• Clarify that the BSO may provide technical review and recommendations regarding containment, containment practices, and risk mitigation measures.
• Clarify that the IBC is responsible for reviewing the proposed containment level, considering the recommendations of the BSO and other subject matter experts as appropriate, and approving the final institutional biocontainment level.
• Specify how differing assessments among the PI, BSO, and IBC should be resolved and identify the institutional authority responsible for the final determination.

ITEM 30: PRESERVE INFLUENZA-SPECIFIC SAFEGUARDS AGAINST UNINTENDED GENOMIC REASSORTMENT
DRAFT REFERENCE: Section IV, experiments involving influenza viruses; current NIH Guidelines, Section III-D-7, Experiments Involving Influenza Viruses.

CONCERN: The draft policy assigns containment for influenza research according to the Risk Group of the virus contributing the majority of genomic segments and establishes enhanced containment for certain 1918 H1N1, human H2N2, and HPAI H5N1 experiments. However, it does not expressly require institutions to evaluate and control the risk of unintended genomic reassortment when different influenza strains are studied concurrently or sequentially in shared rooms, equipment, animal spaces, or supporting systems.

Influenza viruses possess segmented genomes, and concurrent exposure to different strains can create conditions for reassortment. Available federal guidance, such as the BMBL, does not comprehensively address temporal and spatial separation for concurrent or sequential recombinant or synthetic influenza research. USDA APHIS guidance addresses concurrent HPAIV and 1918 influenza studies, but NIH should establish a broader framework for identifying and mitigating unintended reassortment risks involving other consequential strain combinations. This gap illustrates why Risk Group classification alone cannot replace a protocol-specific assessment of the resulting agent, concurrent research activities, shared

spaces and equipment, and credible pathways for unintended reassortment.

REQUESTED ACTION:
• Retain explicit influenza-specific safeguards requiring IBC assessment of unintended genomic reassortment during recombinant, synthetic, reverse-genetics, and reassortant influenza research. The assessment should address concurrent and sequential work, temporal or spatial separation, shared rooms, equipment and animal spaces, validated decontamination between activities, and documented clearance before another influenza strain is introduced.
• Publish influenza-specific implementation guidance identifying the existing safeguards that will be retained, modified, relocated, or discontinued and establishing minimum controls for strain combinations capable of producing a more pathogenic, transmissible, or otherwise consequential reassortant.

ITEM 31: RETAIN A STABLE AND TRANSPARENT RISK GROUP CLASSIFICATION RESOURCE
DRAFT REFERENCE: Section IV, Categories of Oversight for Research Based on Risk; Section V, Risk Assessment and Mitigation for Research Involving Biohazards; NOT-OD-26-112 and the Draft Policy Table of Changes regarding Risk Group classifications as implementation resources.

CONCERN: The draft policy relies on Risk Groups to determine oversight pathways and inform risk assessment but does not retain the agent classification lists contained in the current NIH Guidelines. Moving these classifications to a separate implementation resource creates uncertainty regarding where the authoritative classifications will reside, how changes will be reviewed and communicated, and whether classifications could change without stakeholder notice.

Risk Groups provide an important starting point for biological risk assessment, but they do not independently determine the appropriate containment level for a specific protocol. Final BSL or ABSL determinations must also consider the characteristics of the resulting agent, genetic modifications, experimental procedures, routes of exposure, scale, aerosol potential, animal work, and available safeguards.

REQUESTED ACTION:
• Retain the Risk Group classification lists in the draft policy or in a formally controlled, publicly accessible implementation resource that identifies the authoritative classification, revision date, supporting rationale, and effective date of each material change.
• Establish a transparent process for modifying Risk Group classifications that includes scientific review, advance notice to affected institutions, publication of the basis for the change, and a reasonable implementation period.
• Clarify that Risk Group classification is a starting point for protocol-specific risk assessment and does not automatically determine the final BSL or ABSL, which should be approved by the IBC based on the agent, modifications, procedures, and other relevant risk factors.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The following are suggestions of mechanisms which may encourage voluntary compliance while simultaneously providing benefits to those institutions required

to enroll.

NIH could establish a public-facing voluntary-adoption registry identifying institutions that attest to implementation of specified policy elements. Registrants could reference this verifiable designation in proposals and institutional materials, provided the designation does not imply NIH certification of individual studies or overall institutional performance.

Allow voluntary registrants to have the same access to NIH resources and tech support. As part of NIH implementation, the NIH should provide free policy implementation toolkits (e.g., webinars, templates, checklists) and tech support to any registrant, voluntary or mandatory.

Allow institutions to demonstrate voluntary compliance through existing federal oversight programs that meet equivalent or more stringent requirements. NIH should recognize overlapping controls implemented by FSAP-registered entities and other federally overseen institutions rather than require a separate voluntary enrollment.

Encourage other federal agencies to recognize an NIH voluntary-adoption designation where it is relevant to the agency's own biosafety or research-assurance requirements.

Provide a low burden approach to registration. Allow registrants to adopt the policy in phases specific to their current capacity, and undergo a scheduled external surveillance onsite or remote audit. NIH could accept equivalent inspections, audits, permits, or accreditation findings from applicable oversight programs rather than require a duplicative NIH review. NIH should recognize equivalent requirements and findings from applicable federal programs, including FSAP, the CDC Import Permit Program, and USDA APHIS permit or regulatory oversight. Findings from USDA Animal Care inspections and AAALAC International accreditation may serve as supporting evidence for relevant animal care and use program elements but should not be treated as automatic substitutes for biosafety review.

Following the model of the OSHA Alliance Program, NIH should collaborate with qualified biosafety professional organizations, such as ABSA International, to develop implementation tools, training, technical assistance, and de-identified lessons learned from voluntary early adopters, while retaining responsibility for policy interpretation and oversight.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The following template comments apply independently of Battelle's recommendation to eliminate or substantially limit public posting. If NIH retains the templates for institutional records or confidential NIH oversight, their scope, content, reporting thresholds, and redaction provisions should be revised as described below.

PUBLIC POSTING OF INCIDENT REPORTS AND DETAILED IBC INFORMATION
Public posting of detailed incident reports and meeting minutes could disclose Principal Investigator identities, research agents, locations, exposure pathways, animal husbandry practices, internal processes, and corrective actions. These disclosures could affect operational security, employee privacy, proprietary research, sponsor confidentiality, and institutional reputation, particularly when lower-risk events are presented without context. For CROs, public identification of scientists and staff creates a doxxing risk, while disclosure of agents, methods, or client-related details can destroy confidentiality and

IP protections that sponsors require.
• NIH should use de-identified national summaries and trend reporting as the primary public-transparency mechanism rather than requiring public posting of individual institutional incident reports.
• If institution-level posting is retained, NIH should permit withholding or redaction of personnel, client, proprietary, security-sensitive, facility, location, inventory, and internal-process information.
• NIH should provide a mechanism for non-NIH funded clients to apply for exemption of public identification

REPORTING THRESHOLDS FOR INCIDENTS AND COMPLIANCE VIOLATIONS
Terms such as 'any incident' at BSL-3/ABSL-3 or BSL-4/ABSL-4 and 'any compliance violation' at any BSL/ABSL are too broad to apply consistently. The language could capture administrative deficiencies or equipment events in which redundant systems functioned and containment was maintained.
• NIH should define reportable incident categories using objective criteria tied to actual or credible potential exposure, loss of containment, laboratory-acquired infection, or material public-health consequence.
• NIH should distinguish safety-significant violations from administrative deficiencies and specify which violations require immediate reporting.

DUPLICATION WITH EXISTING REGULATORY REPORTING
The proposed reporting structure overlaps with reporting to the Federal Select Agent Program (FSAP) and other regulatory bodies. Parallel reporting can create inconsistent records and additional administrative burden without a corresponding biosafety benefit.

NIH should coordinate with existing regulatory agencies, such as FSAP, and accept equivalent reporting through established regulatory channels. NIH should not require public posting of security, inventory, or access-control information reported under another federal oversight program.

REDACTION STANDARDS AND POSTING BURDEN
The draft does not provide sufficiently clear redaction standards. Preparing incident reports and minutes for public release would require recurring biosafety, legal, security, communications, and information-technology review.
• NIH should issue presumptive redaction and withholding categories and allow institutions to apply broader redactions when needed to protect personnel, clients, proprietary information, and security.
• NIH should not require duplicative incident reporting when another federal agency is involved in the oversight of the research, specifically the Federal Select Agent Program.
• NIH should account for the administrative burden created by public posting and avoid duplicating information already maintained by regulatory agencies.
• If NIH retains any public-reporting requirement, NIH should maintain a centralized platform limited to de-identified summaries of incidents meeting defined federal reporting thresholds. The platform should not require institutions to publicly post individual incident reports, corrective-action details, personnel identities, or sensitive operational information.

In addition to these comments, please refer to the submitted attachment, including:

ITEM 2: PUBLIC POSTING OF INCIDENT REPORTS
DRAFT REFERENCE: Section III-B, IBC Functions ("Posting all incident reports on a public-facing webpage"); Section III-A (public availability for a minimum of five years); Draft Incident Reporting Template (Redaction and Posting)

CONCERN: The draft policy requires every incident report to be posted publicly, including lower-risk events that are not reportable to NIH. Reports must remain posted for at least five years. Incident reports and the corrective actions they describe necessarily show how an institution's operations, controls and response procedures work. That detail can give malicious actors inside information about sensitive operations. Incident reports are written for a technical audience and do include the context needed to understand them. However, the general public is unlikely to have the specialized biosafety knowledge to interpret that context accurately. A routine, well-managed event can therefore be misread or misinterpreted as a failure. That can create unwarranted concern and may discourage candid reporting of near-misses. The redaction standard is narrow (limited to proprietary or private information and information that would directly compromise institutional or national security), and each institution sets its own criteria.

Additionally, candid reporting of incidents and near-misses is essential to an effective biosafety program; requirements that publicly name the Principal Investigator and the institution may further suppress the reporting needed to identify trends, evaluate safeguards, and prevent recurrence.

REQUESTED ACTION
• Remove the requirement to publicly post individual incident reports and corrective actions.
• Achieve transparency instead through the NIH Annual Incident Summary Report (Section III-D) and de-identified, aggregate analysis, so the public sees trends without institution-level operational detail.
• If any posting is retained, limit it to NIH-reportable incidents that meet defined criteria. Use summary-level, delayed posting. Do not require corrective-action detail. Give institutions explicit authority to withhold security-sensitive information.

ITEM 13: INCIDENT TEMPLATE, “REDACTION AND POSTING OF INCIDENT REPORTS”
DRAFT REFERENCE: "Information that is widely available from other public sources such as institutional webpages, publications describing an investigator's research, or public grants databases (e.g., names of IBC members and PIs, biological agents used in research, including Select Agents, grant numbers) is not considered private or proprietary and may not be redacted from reports."

CONCERN: This provision does not appear to allow institutions to consider the context created by aggregation of otherwise publicly available information. Individual pieces of information may already be public, while combining those data within an incident report could provide substantially greater insight into research activities, biological agents, personnel, incidents, and institutional vulnerabilities.

The explicit inclusion of "biological agents used in research, including Select Agents" raises an especially important security concern.

REQUESTED ACTION:

• Permit institutions to consider the cumulative or aggregated security implications of information when determining whether redaction is appropriate, even when individual elements exist elsewhere in the public domain. Security review should consider the context of the complete incident report, rather than only whether each individual data element has previously been made public.
• Before finalizing the public-disclosure and redaction requirements, obtain review from appropriate federal partners responsible for preventing biological threats and weapons of mass destruction (WMD)-related misuse, including the aggregation of otherwise public information.

ITEM 14: INCIDENT TEMPLATE, PI IDENTIFICATION AND STAFF ID
DRAFT REFERENCE: "Incident reports should not include any personally identifiable identification of individuals involved in the incident (aside from the Principal Investigator's name)." The incident narrative subsequently instructs institutions: "Who was involved in the incident/violation, including others present at the incident location? Note - do not identify individuals by name. Provide only position titles..."

CONCERN: The template protects the identities of personnel involved in an incident but specifically excludes the PI from that protection. Because these reports are required to be publicly posted, naming the responsible PI could unintentionally associate an individual with an incident even when the PI was not present, directly involved, or responsible for the causal factors.

REQUESTED ACTION:
• Remove the requirement of the disclosure of PI names from any publicly posted incident report.
• If NIH oversight requires PI identification, allow institutions to provide the PI identity to NIH while using a role or position designation in the public version, unless identification serves a defined public-health purpose.

ITEM 15: INCIDENT TEMPLATE, REPORTING REQUIREMENTS NOT CALIBRATED TO INCIDENT SEVERITY
DRAFT REFERENCE: "All fields must be fully completed in every final report. If an element does not apply, indicate not applicable."
CONCERN: The template requires the same general level of completion regardless of whether an incident involves:
• A contained BSL-2 exposure with no injury
• A documentation lapse
• A failure of redundant equipment with no release
• A potential laboratory-acquired infection
• A community release
• A major BSL-3 or BSL-4 containment event
A uniform reporting structure does not reflect a meaningful tiered approach based on risk.

REQUESTED ACTION:
• Establish two levels of reporting: 1) Internal institutional record for nonreportable events, with optional de-identified submission to NBDSAC and 2) NIH report for events meeting defined NIH reporting thresholds, with enhanced fields incorporated only when warranted by the severity of the event.
• Assignment to an NIH reporting tier should determine the information provided confidentially to NIH and should not, by itself, require public posting.

ITEM 16: INCIDENT TEMPLATE, OTHER AGENCY REPORTING IS CAPTURED BUT COORDINATION IS NOT
DRAFT REFERENCE: "Has a report of this incident been made to other agencies? If so, indicate: CDC, USDA, FDA, EPA, OSHA."
CONCERN: The checkbox documents that another report occurred but does not address duplication, conflicting timelines, inconsistent definitions, or whether NIH will accept information already submitted to another federal agency. This creates the possibility of multiple reports containing similar information in different formats.
REQUESTED ACTION:
• Accept an equivalent report submitted to another federal oversight agency as satisfying NIH reporting requirements for overlapping elements and require only supplemental information that is uniquely necessary for NIH oversight.
• Coordinate definitions, timelines, and required data elements with other agencies to reduce duplicative oversight.

ITEM 17: MEETING MINUTES TEMPLATE, SHIFTS SUBSTANTIAL LOCAL DELIBERATION INTO A FEDERAL/PUBLIC RECORD
DRAFT REFERENCE: "Institutions must prepare IBC meeting minutes that ... document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities." Points to consider: "In general, the minutes should offer sufficient detail to serve as a record of all major points of discussion and the committee's rationale for decisions." "Key points made in discussion, motions of the committee, and whether those motions were approved should be documented."
CONCERN: Meeting minutes traditionally document committee action, but this template may transform detailed local technical deliberations into publicly available records used by NIH to judge compliance. Effective local oversight depends on committee members being able to discuss uncertainty openly without concern that preliminary statements will be interpreted externally as final findings.
REQUESTED ACTION:
• Require minutes to document the final risk assessment approval, committee decision, and approval conditions.
• A public-facing summary should state the general category of review, confirm that the required assessment occurred, and document the committee’s final action without disclosing sensitive technical or operational details. Do not require a detailed public account of every technical discussion, preliminary concern, or alternative considered.

ITEM 18: MEETING MINUTES TEMPLATE, MAY UNINTENTIONALLY INCLUDE GENERAL SAFETY MATTERS UNRELATED TO COVERED BIOHAZARDS
DRAFT REFERENCE: "All official business conducted at the IBC meeting should be documented using this template." Examples provided: "review of incidents, laboratory inspection reports, reports from safety personnel related to the safe conduct of research at the institution, personnel training, review of policies, etc."
CONCERN: These examples could encompass a broad range of institutional safety matters that are not necessarily connected to research involving biohazards covered by the draft policy. Laboratory inspections, training discussions, and reports from safety personnel frequently address chemical,

physical, radiological, ergonomic, animal-handling, and general occupational hazards. Requiring these discussions to appear in the public IBC record could extend the effective scope of the template beyond biosafety oversight.
REQUESTED ACTION:
• Specify that only the portions of inspection reports, safety discussions, training matters, or policy reviews that materially relate to research subject to the draft policy must be included in the required minutes, and that other institutional safety business remains within the institution's existing oversight and recordkeeping processes.

ITEM 19: MEETING MINUTES TEMPLATE, DELEGATED REVIEW LACKS DEFINED ELIGIBILITY /DOCUMENTATION STANDARDS
DRAFT REFERENCE: "Document all approvals granted by delegated review (may be attached to the minutes as a list). Note any specific issues discussed by the IBC as applicable."
CONCERN: The template does not identify which types of research may be approved through delegated review, who may act as a delegated reviewer, what expertise must be represented, how conflicts of interest must be managed, or whether the full IBC must subsequently ratify the action. Without standardized criteria, institutions may apply delegated review inconsistently, and the minutes may not provide enough information to show why a project was appropriate for review outside the convened committee.
REQUESTED ACTION:
• Define the minimum criteria for delegated review.
• Require the minutes to minimally identify the category of action, basis for delegated review, date of the decision, reviewer role or expertise, approval outcome, conditions imposed, and whether subsequent full-committee action is required.
• Do not require the public version to identify the individual reviewer by name.

ITEM 20: MEETING MINUTES TEMPLATE, HEAVY ADMINISTRATIVE BURDEN
DRAFT REFERENCE: "All official business conducted at the IBC meeting should be documented using this template." The template calls for documentation of institutional information, member attendance, quorum, conflicts, prior business, registrations, delegated reviews, risk assessments, training, occupational-health requirements, biosafety assignments, votes, incidents, inspections, public comments, and additional topics.
CONCERN: The expanded scope of the draft policy, combined with the level of detail required by the meeting minutes template, will substantially increase the administrative time and resources needed to support IBC oversight. Preparing detailed minutes is only one component of this burden. Institutions will also need to review the minutes for accuracy, evaluate information for privacy, proprietary, and security concerns, perform appropriate redactions, obtain IBC approval, maintain the records, and prepare and post a version suitable for public disclosure. As the number of activities requiring IBC oversight increases under the broader draft policy, these requirements will increase workload for IBC members, biosafety staff, PIs, administrative personnel, and other institutional functions supporting review and disclosure. This additional administrative effort should be considered alongside NIH's goal of encouraging compliance. A framework that significantly increases the resources required to administer an IBC program may make voluntary adoption less attractive, even for organizations that otherwise support the draft policy's biosafety principles.

REQUESTED ACTION:
• Exempt non-NIH funded research from mandatory meeting minutes requirements and inclusion may be adopted as voluntary basis only.
• Streamline meeting-minute requirements and ensure that the required level of documentation is proportional to the risk and complexity of the research.
• Provide standardized templates, model language, clear redaction criteria, sample completed minutes, and guidance distinguishing information necessary for the institutional record from information necessary for public disclosure. These measures would reduce unnecessary administrative burden while preserving meaningful documentation, transparency, and biosafety oversight.

ITEM 21: MEETING MINUTES TEMPLATE, ONE DOCUMENTFOR 3 DIFFERENT PURPOSES
DRAFT REFERENCE: "Institutions must prepare IBC meeting minutes that not only serve as the institution's record of the IBC's proceedings but also document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities."
CONCERN: The template expects one document to function as the complete institutional record, evidence of compliance for NIH, and a public transparency document. These purposes require different levels of technical detail, confidentiality, and accessibility. Information necessary for the institution and NIH to evaluate a risk assessment may not be necessary or appropriate for unrestricted public release.
REQUESTED ACTION:
• Establish two related but distinct records: (1) complete institutional minutes available to NIH through a confidential oversight process when requested, and (2) a limited public-facing summary for research subject to the applicable public-disclosure requirement.
• Specify the public summary describes committee actions, principal hazards, final containment decisions, major safeguards, and approval conditions without reproducing sensitive technical or operational details.
• Agent-specific hazards, containment details, safeguards, technical deliberations, and sensitive conditions should remain in the complete institutional record.

ITEM 22: MEETING MINUTES TEMPLATE, INCIDENT INFORMATION MAY BE UNNECESSARILY DUPLICATED
DRAFT REFERENCE: "Document any incidents (e.g., safety incidents, non-compliance issues); If none - state, 'nothing to report.'" The broader draft policy separately requires institutions to post incident reports publicly using the required incident-reporting template.
CONCERN: Requiring incident information in both publicly posted incident reports and publicly posted IBC meeting minutes creates duplicative documentation without a clear additional transparency benefit. The two records may contain different descriptions or redactions, particularly when the IBC discusses an incident before the investigation is finalized. This also increases the risk of premature disclosure and indirect identification of personnel.
REQUESTED ACTION:
• Permit meeting minutes to reference an incident by a unique identifier and document the IBC's review, determination, and resulting actions.
• Use the separate incident-reporting template as the authoritative institutional and NIH record of the event narrative and final findings. Meeting minutes should reference the report by a unique identifier and document only the IBC’s review and resulting actions.

ITEM 23: MEETING MINUTES TEMPLATE, OCC HEALTH REQUIREMENTS
DRAFT REFERENCE: "Document any required occupational health requirements including, but not limited to: Vaccination requirements; Respiratory protection; Periodic review of any medical surveillance; Post-exposure response procedures."
CONCERN: Protocol-level occupational-health requirements can reveal information about expected exposure routes, agent consequences, specialized medical countermeasures, or the health requirements of a small and identifiable employee group. Detailed discussion may also create a risk of disclosing protected medical information.
REQUESTED ACTION:
• The public-facing summary should state only that applicable occupational-health requirements were reviewed and incorporated into the approval. Specific surveillance, vaccination, respiratory-protection, medical, and post-exposure requirements should remain in confidential institutional records.

ITEM 27: “ANY COMPLIANCE VIOLATIONS AT ANY BSL/ABSL” AND THE LACK OF REPORTING GUIDANCE
DRAFT REFERENCE: Section III-B, IBC Functions (reportable incidents include "Any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approval, or failure to obtain NIH approval for lowering biocontainment for research, when required"); Draft Incident Reporting Template
CONCERN:
• The draft policy does not say whether "compliance violations" means violations of the draft policy only, or also violations of requirements enforced by other oversight bodies, such as the Federal Select Agent Program, OSHA, other federal agencies, or state and local authorities. The two examples given are illustrative, not limiting.
• If the broader reading applies, the same event would be reported to multiple bodies with different timelines, definitions and content, and then posted publicly. That duplicates existing oversight and risks inconsistent records of the same event.
• No reporting guidance. The Incident Reporting Template does not appear to include a section or instructions specific to compliance violations. Its fields are built around physical events such as exposures, spills and equipment failures. Institutions therefore have no guidance on what to submit for a compliance event, and the template does not fit one.
• Disproportionate treatment of administrative lapses. Because the term is undefined and applies at any biosafety level, an administrative lapse, such as a late IBC renewal under the three-year approval cycle, could carry the same 24-hour clock and public posting as an exposure event.
REQUESTED ACTION:
• Limit this category to violations of the policy, and enumerate the specific violations that are reportable.
• State that violations reportable to and handled by another oversight body (for exam

6. Other feedback relevant to this resource: CLARIFY VAGUE AND OPEN-ENDED REQUIREMENTS
The draft repeatedly uses terms that leave institutions without objective implementation criteria, including 'as appropriate,' 'as applicable,' 'as needed,' and 'other pertinent information.' The same concern applies to the boundaries of reportable incidents and required institutional disclosures.
• NIH should replace open-ended qualifiers with decision criteria, examples, required data elements, and clear exclusions.
• NIH should release implementation resources with enough time for institutional review and implementation before the effective date.

PUBLIC-DISCLOSURE SAFEGUARDS FOR HIGH-CONTAINMENT PROGRAMS
Requiring public links to institutional biosafety procedures, rosters, training information, incident reports, and information about high-containment capabilities could aggregate security-sensitive information in a single public location.
• NIH should allow institutions to provide detailed program information to NIH through nonpublic channels and limit public disclosure to a high-level statement of compliance. This is a primary value proposition of the NBDSAC, and we recommend that the NIH leverage the NBDSAC function to reduce policy-imposed vulnerabilities generated by the new NIH draft biosafety policy.
• NIH should establish explicit exemptions and redaction provisions for information that could reasonably be expected to reveal research priorities, capabilities, vulnerabilities, or operational details associated with biodefense, medical countermeasure development, public health preparedness, or other activities supporting national security interests, which are not otherwise protected information. When public reporting is necessary, NIH should provide a system for public reporting to promote consistency across reporting entities.
• NIH should consult with appropriate federal law-enforcement and national security partners with biological-threat and WMD responsibilities when establishing public-disclosure, redaction, and withholding requirements, to ensure the Policy does not inadvertently create exploitable security vulnerabilities.

In addition to these comments, please refer to the submitted attachment for a more detailed discussion of the concerns and recommended actions for NIH consideration. For clarity, these associated concerns are as follows:

ITEM 5: “OTHER PERTINENT INFORMATION REQUESTED BY NIH”
DRAFT REFERENCE: Section III-A, Responsibilities of the Institution (final bullet: "other pertinent information requested by NIH"), in the Biosafety Assurance submission requirements.

CONCERN: The Assurance must list its required elements, but this bullet adds an unlimited category on top of them. The draft policy does not say what NIH may request, why, how often, or how quickly the institution must respond. This matters because NIH approval of the Assurance is a precondition for conducting any covered research. An open-ended information request could delay or withhold that approval, with no stated standard for when the Assurance is complete and no review deadline. The institution would have no way to know in advance whether its submission is sufficient.

The word "pertinent" is undefined and is decided by NIH alone. Institutions cannot prepare for, budget for, or plan around a requirement they cannot see. The Assurance is also valid for a limited period (up to four years), so the uncertainty recurs at each renewal. Additionally, NIH could request security-sensitive or proprietary information, such as facility design, inventories, personnel details or sponsor-restricted work. The draft policy gives no limits on such requests and no stated protection for what institutions submit.

REQUESTED ACTION:
• Delete "other pertinent information requested by NIH," or replace it with a closed, enumerated list of required Assurance elements.

• If NIH needs to retain authority for follow-up requests, limit it to information necessary to evaluate compliance with a specific provision of the draft policy. NIH should state the purpose of the request in writing.
• Give institutions a reasonable response period, and have NIH act on the Assurance within a fixed review deadline once the listed elements are submitted.
• State that institutions may withhold, or provide in redacted form, security-sensitive, proprietary or sponsor-restricted information, and that NIH will protect submitted information from public release to the extent permitted by law, consistent with the request in Item 1.

ITEM 6: NIH REVIEW AND RESPONSE TIMELINES, “IN A TIMELY MANNER”
DRAFT REFERENCE: Section III-D, Responsibilities of the National Institutes of Health (bullets on "[r]eviewing requests for lowering containment levels in a timely manner" and "[r]eviewing and responding in a timely manner to reports of incidents subject to the Policy"; related bullets on determining containment levels for emerging, novel or zoonotic agents, approving or withdrawing Assurances, and verifying institutional incident responses)

CONCERN: The draft policy imposes specific deadlines on institutions, including a 24-hour notification and a 30-day full report for certain incidents. NIH's own obligations are limited to "a timely manner," which the draft policy does not define. The obligations are not reciprocal, and institutions cannot plan around an undefined standard. NIH determinations are gating steps. Research cannot start under an unapproved Assurance, and requests to lower containment or to determine containment for emerging, novel or zoonotic agents remain pending with the NIH. Without a deadline, a delay on NIH's side can stall research indefinitely, with no stated mechanism to escalate or appeal. Transparent and predictable NIH review timelines would improve accountability, reduce administrative burden, and support efficient oversight without reducing biosafety protections.

For incidents, NIH's response and its verification of the institution's corrective action have no stated timeframe. Institutions cannot close out an incident, confirm that corrective actions are accepted, or know whether NIH will require further action. If public posting is retained, the incident report template calls for posting NIH's final response, so an open-ended NIH response time leaves incidents open on the public record.

As written, the draft policy does not provide an expedited review pathway for urgent circumstances. This includes emerging public health concerns, sponsor-driven timelines, or situations where a delayed review could adversely affect critical research activities.

REQUESTED ACTION:
• Require NIH to notify the institution whether a submission is complete or identify all known deficiencies needed to begin a substantive review.
• Define "timely manner" in the draft policy with fixed timeframes for each NIH action. For example: acknowledge receipt of an incident report within 5 business days and provide an initial response within 30 days; act on containment-lowering requests within 60 days; act on Assurances within 90 days of a complete submission.

• Require NIH to provide periodic status updates for reviews and maintain a mechanism for institutions to track the status of pending submissions.
• Provide an interim path when NIH misses a deadline. Institutions should be able to continue approved work under IBC oversight while an Assurance is pending. For containment requests, work stays at the existing containment level until NIH acts, and the institution can request a status update and escalation.
• Set a deadline for NIH to verify an institution's incident response or state what additional action is required. Provide a way to close out an incident once corrective actions are accepted.
• Establish a documented process, standard and appeal path before NIH restricts or withdraws approval of an Assurance, including written notice of the basis and a reasonable opportunity to respond.
• Require NIH to publish its performance against these timeframes in the NIH Annual Incident Summary Report.
• Establish a formal escalation process for expedited review when needed, such as for emerging public health concerns.

ITEM 26: OPEN-ENDED NIH INTERPRETIVE AUTHORITY AND RELIANCE ON LATER GUIDANCE
DRAFT REFERENCE: Section III-D, Responsibilities of the NIH (bullets on "[p]romulgating requirements and guidance necessary to implement the NIH Biosafety Policy," "[i]nterpreting this Policy for cases in which the Policy does not specifically assign containment levels," restricting or withdrawing approval of Assurances, and verifying and directing institutional incident responses); Compliance and Enforcement ("including, but not limited to"); Draft Incident Reporting Template ("additional measures to be taken as appropriate"); NOT-OD-26-112 (Risk Group classifications and other requirements to be provided as implementation resources)

CONCERNS:
• Requirements set outside the draft policy. The draft policy leaves key requirements to later guidance and NIH interpretation. These include Risk Group classifications, containment and training requirements for certain work, and containment for agents the draft policy does not assign. Institutions are asked to comment on a draft policy whose operative details are not yet defined, and those details could change without further public input.
• Standards defined after the fact. Several terms that determine what is reportable and what counts as compliance are undefined, including "significant risk to human health," "incident," "any compliance violations," and "timely manner." NIH's authority to interpret the draft policy and to verify that an institution's response "is appropriate" would give those terms their practical meaning case by case, after events occur.
• Interpretation, enforcement, and standard-setting in one party. NIH issues guidance, interprets gaps, judges compliance, and decides on enforcement, with no stated appeal path, deadline, or requirement to publish its interpretations. Institutions cannot know in advance what will satisfy NIH.
• Compliance exposure. Compliance is a term and condition of award, and enforcement can affect future funding. An institution acting in good faith on a reasonable reading could face action if NIH later reads the draft policy differently.
• Open-ended consequences. "Including, but not limited to" and "as appropriate" leave the range of NIH's required actions and enforcement responses undefined.
• Inconsistent application. Without published interpretations, NIH could treat similar facts differently

across institutions, and institutions could not learn from one another's determinations.

REQUESTED ACTION:
• Place in the draft policy text, not in later guidance, the elements that determine scope, review tier, containment, reporting, and compliance. These include Risk Group classifications and the definitions listed in the related items.
• Provide for public notice and comment before implementation resources or guidance that create or change requirements take effect, and state that such guidance is not binding unless it has gone through that process.
• Require NIH to publish its interpretations and determinations of general applicability, and to give written reasons for individual determinations.
• Provide a good-faith compliance provision: an institution that acts on a reasonable, documented interpretation of the draft policy or of published NIH guidance will not face enforcement for that interpretation.
• Establish a process for institutions to request a written interpretation from NIH, with a response deadline, and a reconsideration and appeal path for adverse determinations.
• Provide advance notice and a reasonable transition period when NIH guidance changes requirements, and limit retroactive application.
• Replace "including, but not limited to" and "as appropriate" with defined lists of possible actions and the circumstances for each.

Uploaded File: Battelle-RFI_Draft-NIH-Biosafety-Policy.pdf

Description: Attached is the summary of all of the comments

Battelle Memorial Institute Response to Request for Information: Draft NIH Biosafety Policy for Research Involving Biohazards

Policy	Request for Information on Draft NIH Biosafety Policy for Research Involving Biohazards
Notice	NOT-OD-26-112
Comment deadline	October 19, 2026
Submitted by	Battelle Memorial Institute

Introduction

Battelle Memorial Institute (Battelle) is an independent, nonprofit applied science and technology organization whose mission is to advance scientific discovery and innovation for the benefit of society through research, development, education, and the responsible application of science. For nearly a century, Battelle has conducted research addressing challenges in public health, national security, environmental stewardship, and other fields where the safe and responsible conduct of research is essential.

Battelle's comments are informed by decades of experience conducting biological research and managing the associated scientific, biosafety, biosecurity, operational, and regulatory responsibilities necessary to support complex research programs. Battelle's experience includes research, development, testing, and evaluation activities supporting medical countermeasures, biodefense and CBRNE preparedness efforts, force health protection, and public health readiness initiatives intended to address emerging biological and chemical threats.

Consistent with its mission and longstanding commitment to the responsible conduct of research, Battelle offers the following observations and recommendations for consideration as NIH refines the Draft NIH Biosafety Policy for Research Involving Biohazards. The comments focus on institutional scope, regulatory clarity, public disclosure requirements, incident-reporting expectations, alignment with existing federal oversight programs, and implementation considerations, with particular attention to minimizing unintended operational, administrative, security, and compliance impacts.

Item 1: Public disclosure of program details through the Biosafety Assurance Submissions

Draft reference: Section III-A (Assurance submissions: weblinks "to the maximum extent possible" to procedures, a continuously updated IBC roster, minutes, processes for how biosafety risks are managed, incident reports, training synopses; whether the institution conducts BSL-3/4 research).

Concern: The Assurance would direct the public to a consolidated profile of each institution, including where high-containment work is conducted. This information supports transparency, but it is equally useful to those who wish to target personnel, disrupt operations, or gain inside knowledge of how a program functions.

Procedures and incident reports are written for a technical audience and do include the context needed to understand them. However, the general public is unlikely to have the specialized biosafety knowledge to interpret that context accurately, so these documents are likely to be misread or misinterpreted. Continuous updating and long retention increase both risks. The draft policy contains no express authority to withhold security-sensitive material from the public weblinks.

Requested action:

- Remove the expectation that the Assurance submissions link to public postings of procedures, processes for how biosafety risks are managed, rosters, minutes, training synopses and incident reports.
- Allow institutions to provide this information to NIH confidentially, with public disclosure limited to a high-level institutional attestation of compliance.
- Do not require public identification of BSL-3/4 or GDMO capability at the institution level.
- State expressly that institutions may withhold security-sensitive information, and require that NIH protect submitted Assurances from public release to the extent permitted by law.
- Allow institutions to submit the same information already submitted to other federal regulatory programs (e.g., the Federal Select Agent Program) rather than creating duplicate or conflicting information.

Item 2: Public posting of incident reports and corrective actions

Draft reference: Section III-B, IBC Functions ("Posting all incident reports on a public-facing webpage"); Section III-A (public availability for a minimum of five years); Draft Incident Reporting Template (Redaction and Posting)

Concern: The draft policy requires every incident report to be posted publicly, including lower-risk events that are not reportable to NIH. Reports must remain posted for at least five years. Incident reports and the corrective actions they describe necessarily show how an institution's operations, controls and response procedures work. That detail can give malicious actors inside information about sensitive operations. Incident reports are written for a technical audience and do include the context needed to understand them. However, the general public is unlikely to have the specialized biosafety knowledge to interpret that context accurately. A routine, well-managed event can therefore be misread or misinterpreted as a failure. That can create unwarranted concern and may discourage candid reporting of near-misses. The redaction standard is narrow (limited to proprietary or private information and information that would directly compromise institutional or national security), and each institution sets its own criteria.

Additionally, candid reporting of incidents and near-misses is essential to an effective biosafety program; requirements that publicly name the Principal Investigator and the institution may further suppress the reporting needed to identify trends, evaluate safeguards, and prevent recurrence.

Requested action:

- Remove the requirement to publicly post individual incident reports and corrective actions.

- Achieve transparency instead through the NIH Annual Incident Summary Report (Section III-D) and de-identified, aggregate analysis, so the public sees trends without institution-level operational detail.
- If any posting is retained, limit it to NIH-reportable incidents that meet defined criteria. Use summary-level, delayed posting. Do not require corrective-action detail. Give institutions explicit authority to withhold security-sensitive information.

Item 3: "Incident" and "significant risk to human health" are undefined, and "any incident" at BSL-3/ABSL-3 and BSL-4/ABSL-4 is open-ended

Draft reference: Section III-B, IBC Functions (reportable incidents "pose a significant risk to human health"; "any incident" at BSL-3/ABSL-3 or BSL-4/ABSL-4; 24-hour notification to NIH)

Concern: Section III-B states that reportable incidents are those that "pose a significant risk to human health." The draft policy defines neither "incident" nor "significant risk to human health," and it gives no objective test for either. The list then covers "any incident" at BSL-3/ABSL-3 and BSL-4/ABSL-4. The list is introduced with "including," but "any" combined with an undefined term can reasonably be read to capture every event at those levels, regardless of risk. The word "any" also contradicts the stated "significant risk" threshold. The likely results are subjective and inconsistent determinations across institutions, over-reporting, and a 24-hour clock applied to events that do not pose a significant risk to human health.

Requested action:

- Define "incident" in the draft policy with objective criteria.
- Define "significant risk to human health" and use it as the single threshold for every reportable category.
- Replace "any incident" at BSL-3/ABSL-3 and BSL-4/ABSL-4 with a closed, enumerated list of reportable event types. Examples are confirmed or potential laboratory-acquired infection, overt exposure (as defined by NIH), and loss of containment with potential for exposure.
- Provide decision criteria and examples for events below the threshold. State that these are documented and handled internally under IBC oversight rather than reported to NIH or publicly posted.

Item 4: "Biological agent inventory and security issues that may have public health consequences"

Draft reference: Section III-B, IBC Functions (BSL-3/ABSL-3 and BSL-4/ABSL-4 incident list)

Concern: The phrase "may have public health consequences" is speculative and has no objective test, because almost any inventory or security event could arguably meet it. Inventory and security events involving select agents and toxins are already governed by the Federal Select Agent Program (42 CFR Part 73; 7 CFR Part 331; 9 CFR Part 121). A parallel 24-hour NIH report, followed by public posting, duplicates that oversight. It also publicizes security information that is normally protected and could be exploited by malicious actors.

Requested action:

- Exclude agents regulated under the Federal Select Agent Program from this category, and defer to that program and other applicable security regimes.
- If any version is retained, replace "may have public health consequences" with an objective standard.
- State explicitly that inventory, security and access-control information is excluded from any public posting.

Item 5: "Other pertinent information requested by NIH"

Draft reference: Section III-A, Responsibilities of the Institution (final bullet: "other pertinent information requested by NIH"), in the Biosafety Assurance submission requirements.

Concern: The Assurance must list its required elements, but this bullet adds an unlimited category on top of them. The draft policy does not say what NIH may request, why, how often, or how quickly the institution must respond. This matters because NIH approval of the Assurance is a precondition for conducting any covered research. An open-ended information request could delay or withhold that approval, with no stated standard for when the Assurance is complete and no review deadline. The institution would have no way to know in advance whether its submission is sufficient.

The word "pertinent" is undefined and is decided by NIH alone. Institutions cannot prepare for, budget for, or plan around a requirement they cannot see. The Assurance is also valid for a limited period (up to four years), so the uncertainty recurs at each renewal. Additionally, NIH could request security-sensitive or proprietary information, such as facility design, inventories, personnel details or sponsor-restricted work. The draft policy gives no limits on such requests and no stated protection for what institutions submit.

Requested action:

- Delete "other pertinent information requested by NIH," or replace it with a closed, enumerated list of required Assurance elements.
- If NIH needs to retain authority for follow-up requests, limit it to information necessary to evaluate compliance with a specific provision of the draft policy. NIH should state the purpose of the request in writing.
- Give institutions a reasonable response period, and have NIH act on the Assurance within a fixed review deadline once the listed elements are submitted.
- State that institutions may withhold, or provide in redacted form, security-sensitive, proprietary or sponsor-restricted information, and that NIH will protect submitted information from public release to the extent permitted by law, consistent with the request in Item 1.

Item 6: NIH review and response timelines ("in a timely manner")

Draft reference: Section III-D, Responsibilities of the National Institutes of Health (bullets on "[r]eviewing requests for lowering containment levels in a timely manner" and "[r]eviewing and responding in a timely manner to reports of incidents subject to the Policy"; related bullets on determining containment levels for

emerging, novel or zoonotic agents, approving or withdrawing Assurances, and verifying institutional incident responses)

Concern: The draft policy imposes specific deadlines on institutions, including a 24-hour notification and a 30-day full report for certain incidents. NIH's own obligations are limited to "a timely manner," which the draft policy does not define. The obligations are not reciprocal, and institutions cannot plan around an undefined standard. NIH determinations are gating steps. Research cannot start under an unapproved Assurance, and requests to lower containment or to determine containment for emerging, novel or zoonotic agents remain pending with the NIH. Without a deadline, a delay on NIH's side can stall research indefinitely, with no stated mechanism to escalate or appeal. Transparent and predictable NIH review timelines would improve accountability, reduce administrative burden, and support efficient oversight without reducing biosafety protections.

For incidents, NIH's response and its verification of the institution's corrective action have no stated timeframe. Institutions cannot close out an incident, confirm that corrective actions are accepted, or know whether NIH will require further action. If public posting is retained, the incident report template calls for posting NIH's final response, so an open-ended NIH response time leaves incidents open on the public record.

As written, the draft policy does not provide an expedited review pathway for urgent circumstances. This includes emerging public health concerns, sponsor-driven timelines, or situations where a delayed review could adversely affect critical research activities.

Requested action:

- Require NIH to notify the institution whether a submission is complete or identify all known deficiencies needed to begin a substantive review.
- Define "timely manner" in the draft policy with fixed timeframes for each NIH action. For example: acknowledge receipt of an incident report within 5 business days and provide an initial response within 30 days; act on containment-lowering requests within 60 days; act on Assurances within 90 days of a complete submission.
- Require NIH to provide periodic status updates for reviews and maintain a mechanism for institutions to track the status of pending submissions.
- Provide an interim path when NIH misses a deadline. Institutions should be able to continue approved work under IBC oversight while an Assurance is pending. For containment requests, work stays at the existing containment level until NIH acts, and the institution can request a status update and escalation.
- Set a deadline for NIH to verify an institution's incident response or state what additional action is required. Provide a way to close out an incident once corrective actions are accepted.
- Establish a documented process, standard and appeal path before NIH restricts or withdraws approval of an Assurance, including written notice of the basis and a reasonable opportunity to respond.
- Require NIH to publish its performance against these timeframes in the NIH Annual Incident Summary Report.

- Establish a formal escalation process for expedited review when needed, such as for emerging public health concerns.

Item 7: Application of the draft policy to non-NIH-funded research at any institution receiving any NIH funding

Draft reference: Section II, Scope ("This Policy is also applicable to non-NIH funded research that is conducted on or after [effective date] at an institution that receives any NIH funding"; the Scope also applies "regardless of NIH funding level or funding mechanism"); Compliance and Enforcement (institutions "shall ensure that any research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with this Policy"); General Definitions, "Biomedical research" (includes "non-NIH funded research that is conducted at an institution that receives any NIH funding"); Section III-A (no research subject to the draft policy may be conducted until NIH approves the institution's Biosafety Assurance)

Concern:

- Overreach. The draft policy already defines "NIH-supported research" as all research funded in whole or in part by NIH. It then extends the draft policy to every other research program at the institution. A single NIH award of any size, through any mechanism, would pull in the institution's entire portfolio, including work funded by other federal agencies and private clients. Institutions that draw funding from many sources are affected most and are disproportionately impacted. The connection between receipt of NIH funding for one project and regulation of unrelated research activities elsewhere within the institution is not clearly articulated.
- Contractors, collaborators and shared facilities. The draft policy also, as written, does not address how obligations apply to contractors, subcontractors, collaborators, partnerships, or shared facilities. There may be conflicting oversight obligations when only some participating organizations receive NIH funding.
- Existing oversight. Much of this work is already overseen by its own sponsors and regulators, especially at the federal level. These sponsors often require comparable biosafety documentation, reviews and incident reporting. Applying NIH requirements on top creates duplicate review and reporting, and it can produce conflicting findings and timelines. The deference language in Section II refers only to "another federal agency," does not define the "approvals or other applicable clearances" required, and does not address private sponsors.
- Financial burden. Institutions would have to submit and maintain an Assurance, put additional protocols through IBC review, complete incident reports, and publicly post information for programs that NIH does not fund. The notice materials do not include a cost estimate for this expansion, and the costs would fall on institutions and, through them, on non-NIH sponsors. Low-risk non-NIH-funded projects may become subject to the same administrative burdens as activities that present substantially greater biosafety risk.
- Delay. The draft policy bars all covered research until NIH approves the Assurance, and it sets no review deadline for NIH. Because the draft policy reaches non-NIH work, an NIH delay could stall sponsor programs that have fixed contract schedules and deliverables, even though NIH is not funding or directing the work.

- Sponsor restrictions. Public posting and disclosure requirements can conflict with confidentiality, proprietary-information, controlled unclassified information, export-control and security terms in sponsor agreements. An institution cannot unilaterally breach those terms, and the draft policy provides no mechanism to reconcile them.
- Classified work. The draft policy does not address government-classified research. Classified programs cannot be disclosed in an Assurance, in IBC minutes or incident reports, or on a public website. The existence of such work may itself be restricted. The draft policy's redaction language covers information that would "directly compromise institutional or national security," but only for the public posting of reports. It does not address the Assurance, IBC review, NIH reporting, or the personnel and clearances needed to review such material. Without accommodation, institutions with classified programs cannot show compliance without violating their security obligations.
- Enforcement exposure on non-NIH work under undefined standards. The draft policy states that failure to comply "may provide a basis for enforcement actions, including, but not limited to, additional special terms and conditions, or termination," and that enforcement "may affect future funding decisions for the recipient institution." Because the draft policy extends to non-NIH-funded work, an institution's NIH funding could be put at risk over research that NIH does not fund. The standards against which compliance would be judged are not yet defined. Examples include what "pose[s] a significant risk to human health"; what counts as an "incident" or as "any compliance violations"; what "a timely manner" means (the same draft policy that leaves NIH's response time undefined); what "other pertinent information" must be provided; and what redactions are "appropriate and allowable." Institutions cannot reliably demonstrate compliance with terms they must interpret on their own, and two institutions could reach different, equally reasonable readings. The phrase "including, but not limited to" also leaves the range of possible enforcement actions open. Enforcement consequences this significant should rest on requirements that are clear, objective and known in advance.
- Competitive impact. The draft policy could create an uneven competitive landscape. Institutions that receive NIH funding would incur additional oversight, reporting, Assurance, and public disclosure obligations across their research portfolio, while institutions conducting comparable non-NIH-funded work without NIH funding would not. This may discourage participation in NIH-funded research and create incentives to separate research activities among affiliated entities.
- Commercial sponsor impact. Commercial sponsors may be unwilling to place proprietary research at institutions subject to mandatory public posting or NIH oversight on non-NIH-funded work. This could reduce research opportunities and increase costs for institutions and sponsors.

<u>Requested action:</u>

- Limit the draft policy to NIH-supported research as the draft policy already defines it. Delete the non-NIH-funded sentence in Section II, the "irrespective of the source of funding" language in Compliance and Enforcement, and the non-NIH clause in the "Biomedical research" definition.
- Continue to encourage voluntary adoption for other research, as the Voluntary Compliance section already provides.
- If NIH retains institution-wide application, require that it apply at the project or facility level, not through one institution-wide gate. Exempt research already overseen by another federal agency or by

sponsor-required biosafety oversight from NIH review, incident reporting and public posting, and accept the other oversight body's documentation as meeting NIH's requirement.

- If NIH retains institution-wide application, exempt non-NIH-funded projects already underway before the effective date.
- Add an express provision for classified research. It should state that classified work is overseen under applicable national security requirements. It should also say that nothing in the draft policy requires disclosure of classified information, including the existence of the work, in an Assurance, in IBC records, or in any report to NIH or the public. Provide a compliance pathway that does not depend on disclosure.
- Provide an exemption or a defined process for sponsor-restricted work (proprietary, controlled unclassified, export-controlled or contractually confidential), with no public posting.
- Clarify whether the draft policy applies to contractors, subcontractors, and shared facilities.
- Do not gate research that NIH does not fund on NIH approval of the Assurance. If any non-NIH work stays in scope, set fixed NIH review deadlines and allow work to continue under existing sponsor and IBC oversight while review is pending.
- Publish a cost and burden analysis specifically for the expansion to non-NIH-funded research.
- Define the terms listed above in the draft policy before any enforcement authority applies, and tie each enforcement action to a specific, enumerated requirement.
- Limit enforcement actions affecting NIH funding to NIH-supported research. Do not link NIH funding decisions to compliance on non-NIH-funded work.
- Establish a graduated, documented enforcement process: written notice of the specific requirement allegedly not met, a reasonable opportunity to respond and correct, and an appeal path before any special terms, termination or funding consequence.
- Provide a good-faith compliance provision. Institutions that make a reasonable, documented interpretation of an undefined term would not face enforcement while NIH is still issuing implementation guidance.
- Replace "including, but not limited to" with a defined list of possible enforcement actions.

Item 8: Reporting of "potential releases" from facility or equipment failures "even when redundant systems were functioning properly"

Draft reference: Section III-B, IBC Functions (reportable incidents at BSL-3/ABSL-3 or BSL-4/ABSL-4: "potential releases involving facility and/or equipment failures, even when redundant systems were functioning properly, to address the possibility of risk to personnel and the community and prevent future occurrences"); Section III-C (voluntary, confidential near-miss reporting to the National Biosafety Data and Safety Analysis Center)

Concern:

- Circular trigger. Redundant systems exist to prevent releases. When they function properly, no release occurs. The clause nevertheless requires a report of a "potential release," so the trigger depends on something that did not happen. The draft policy does not define "potential release," so institutions cannot tell what counts. Requiring a report when backup systems perform exactly as designed treats successful risk mitigation as evidence of a reportable incident rather than a demonstration that the

containment system functioned properly. In addition, public reporting of events in which containment was never lost may create the appearance of a biosafety failure where none occurred.

- Inconsistent with the "significant risk" threshold. Section III-B limits reportable incidents to those that "pose a significant risk to human health." A failure that a redundant system contained does not meet that threshold, and the draft policy does not reconcile the two.
- Undefined scope. "Facility and/or equipment failures" has no limits. Without a definition, a wide range of routine faults and maintenance events could become reportable. That would drive over-reporting, inconsistent determinations across institutions, and a heavy burden of review, reporting and public posting. A high volume of low-risk reports could divert attention from events involving actual exposures, releases, or containment failures.
- Disincentive to good design and candid reporting. Treating a successful backup as a reportable event discourages institutions from recording and discussing equipment faults openly. That works against NIH's stated aim of learning from near-misses.
- Inconsistent with the voluntary near-miss framework. The draft encourages voluntary, confidential reporting of near-misses and secondary failures to the National Biosafety Data and Safety Analysis Center, and it says NIH will not use that data for enforcement unless there was an environmental release or lab acquired infection. This clause requires essentially the same kind of event to be reported to NIH, and posted publicly, under the mandatory process.
- Overlap with existing oversight. Facility and equipment performance is already governed by existing biosafety, facility-maintenance and, where applicable, Federal Select Agent Program requirements. The draft does not say how this reporting relates to them.

Requested action:

- Delete "even when redundant systems were functioning properly." Events in which secondary or redundant controls performed as designed should not be reportable to NIH.
- Limit this category to equipment or facility failures that result in a loss of containment, an actual release, or an exposure, or that create a documented potential for exposure that safeguards did not prevent. Define "potential release" with objective criteria.
- Handle failures in which redundant systems held as internal events, reviewed by the IBC and documented locally, as the draft already does for lower-risk incidents that "must be reported to and addressed by the IBC" but not NIH.
- Direct near-miss and secondary-failure information to the voluntary, confidential framework in Section III-C, with the protections stated there. Do not make it a mandatory, publicly posted report.
- Define "facility and/or equipment failure" using objective, risk-based criteria such as loss of primary containment, loss of negative pressure beyond established limits, failure of decontamination systems, or failure resulting in actual exposure or release. Align any retained reporting with existing federal requirements, so one event does not trigger parallel reports.

Item 9: Records retention and duration of public availability

Draft reference: Section III-A (records retention "in accordance with Section 8.4.2 of the NIH GPS … 2 CFR 200.334," and "IBC meeting minutes and incident reports must be publicly posted for a minimum of five years";

incident reports and minutes containing award-related records "must be made available to the public during this time if requested")

Concern:

- Separate obligations, mismatched periods. The draft policy ties records retention to the federal baseline of three years under 2 CFR 200.334 and NIH GPS 8.4.2, then sets a separate five-year public posting requirement. The two are different obligations, and the draft policy gives no safety rationale for the longer public period.
- Exceeds the federal baseline. 2 CFR 200.334 provides that Federal agencies "may not impose any other record retention requirements" except for specified circumstances. The draft policy does not identify which exception supports a five-year requirement.
- No defined start date. The draft policy does not say when the five years begin (posting date, meeting or incident date, or award closeout). Incident reports can span multiple protocols at different stages of the grant cycle, so institutions cannot determine when posting may end.
- Unclear scope. The draft policy uses both "publicly posted" and "made available to the public … if requested." It does not say which applies to which records, or what happens when a record is only partly award-related.
- Added risk and cost. A longer public window increases the aggregation and security risks as well as hosting, review and redaction costs. It also prolongs the risk of misinterpretation by non-expert audiences. NIH already has access to retained records for as long as they are kept, so extended public posting is not needed for NIH oversight.
- Non-NIH work. For research that NIH does not fund, no federal award exists, so the retention baseline does not apply, yet the five-year public requirement would.
- Record accuracy. The draft policy does not address whether corrected reports, amended findings, or updated corrective actions replace prior versions, nor does it explain which versions remain publicly available. Retaining outdated information for extended periods could create inaccurate public record, especially as biosafety practices and facility capabilities change over time.

Requested action:

- Align any public availability period with the existing three-year baseline, or remove the fixed minimum, and keep records for NIH access under existing retention rules.
- If NIH retains a longer public period, state the safety rationale and the legal basis, including which provision of 2 CFR 200.334 permits it.
- Define when the period starts and ends, and how it applies to records spanning multiple protocols or awards.
- Clarify which records must be continuously posted and which need only be provided on request, and permit removal after the period ends.
- Clarify when and how records are updated throughout the reporting process.
- Exempt non-NIH-funded research from the public availability requirement.

Item 10: Definition of "Biomedical research" as research "within the mission of the NIH"

Draft reference: General Definitions, "Biomedical research" ("Research on a topic that is within the mission of the NIH," including non-NIH-funded research conducted at an institution that receives NIH funding); Section II, Scope. The draft policy repeatedly conditions applicability on "research," but does not provide a general definition of "research" itself, and the separate definition of "laboratory research" addresses only where the work occurs.

Concern: For institutions that conduct multidisciplinary research, these provisions create uncertainty regarding independently sponsored defense, commercial, veterinary, environmental, product-development, validation, quality-control, surveillance, and similar activities. Applicability also turns on "known or potential risk to human health," which the draft policy does not define, so it is unclear how these activities are treated where human health is not the focus of the work.

Because coverage determines whether an Assurance, IBC review, incident reporting and public posting apply, and because enforcement can affect NIH funding, institutions need to know in advance which activities are covered. The same definition is also the basis for extending the draft policy to non-NIH-funded research.

Requested action:

- Provide objective criteria and representative examples for determining when independently sponsored work is sufficiently within the NIH mission to constitute covered biomedical research.
- Define "research" for policy applicability and distinguish it from operational testing, validation, quality control, manufacturing support, diagnostics, training, and other related biological activities.
- Establish a formal process for institutions to request written applicability or scope determinations for ambiguous projects and activities.

Item 11: Reliance on other federal oversight, including the Federal Select Agent Program

Draft reference: Section II, Scope states, "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." Section V-A separately recognizes that the Federal Select Agent Program oversees the possession, use, and transfer of Select Agents and Toxins and states, "All entities must follow the requirements laid out in the Select Agent Regulations."

Concern: Although Section V-A names the Federal Select Agent Program, the draft policy does not say whether it is a qualifying program under Section II, what approvals or clearances are required, whether other federal oversight replaces or supplements NIH requirements, or which NIH requirements continue to apply.

Requested action:

- Identify qualifying agencies and programs, including the Federal Select Agent Program, and define the approvals or clearances required.

- Establish a formal reliance or equivalency framework that identifies which NIH requirements are satisfied by another federal oversight program and how duplicative or conflicting requirements will be resolved.
- State whether work under another federal agency's oversight remains subject to NIH incident reporting, public posting and IBC review.

Item 12: Three-year de novo approval requirement

Draft reference: Section III-B (IBC Functions) requires the IBC to periodically review approved research and states that approval may not exceed three years, at which time a de novo registration submission and review is required. Changes that may affect the original biosafety assessment must be reviewed before implementation.

Concern: The draft policy does not define the frequency, scope, or documentation for periodic review. Requiring a complete de novo submission every three years for unchanged, compliant, lower-risk research may divert resources from higher-risk oversight without a corresponding improvement in risk control.

Requested action:

- Define periodic-review expectations based on risk, compliance history, complexity, and whether material changes have occurred.
- Permit streamlined renewal or administrative continuation for unchanged, compliant research and reserve full de novo review for material changes, elevated-risk work, significant incidents, or compliance concerns.

Item 13: Incident Template - "Redaction and Posting of Incident Reports"

Draft reference: "Information that is widely available from other public sources such as institutional webpages, publications describing an investigator's research, or public grants databases (e.g., names of IBC members and PIs, biological agents used in research, including Select Agents, grant numbers) is not considered private or proprietary and may not be redacted from reports."

Concern: This provision does not appear to allow institutions to consider the context created by aggregation of otherwise publicly available information. Individual pieces of information may already be public, while combining those data within an incident report could provide substantially greater insight into research activities, biological agents, personnel, incidents, and institutional vulnerabilities.

The explicit inclusion of "biological agents used in research, including Select Agents" raises an especially important security concern.

Requested action:

- Permit institutions to consider the cumulative or aggregated security implications of information when determining whether redaction is appropriate, even when individual elements exist elsewhere in the

public domain. Security review should consider the context of the complete incident report, rather than only whether each individual data element has previously been made public.
- Before finalizing the public-disclosure and redaction requirements, obtain review from appropriate federal partners responsible for preventing biological threats and weapons of mass destruction (WMD)-related misuse, including the aggregation of otherwise public information.

Item 14: Incident Template - Principal Investigator identification and staff identification

Draft reference: "Incident reports should not include any personally identifiable identification of individuals involved in the incident (aside from the Principal Investigator's name)." The incident narrative subsequently instructs institutions: "Who was involved in the incident/violation, including others present at the incident location? Note - do not identify individuals by name. Provide only position titles..."

Concern: The template protects the identities of personnel involved in an incident but specifically excludes the PI from that protection. Because these reports are required to be publicly posted, naming the responsible PI could unintentionally associate an individual with an incident even when the PI was not present, directly involved, or responsible for the causal factors.

Requested action:

- Remove the requirement of the disclosure of PI names from any publicly posted incident report.
- If NIH oversight requires PI identification, allow institutions to provide the PI identity to NIH while using a role or position designation in the public version, unless identification serves a defined public-health purpose.

Item 15: Incident Template - Reporting requirements not calibrated to incident severity

Draft reference: "All fields must be fully completed in every final report. If an element does not apply, indicate not applicable."

Concern: The template requires the same general level of completion regardless of whether an incident involves:

- A contained BSL-2 exposure with no injury
- A documentation lapse
- A failure of redundant equipment with no release
- A potential laboratory-acquired infection
- A community release
- A major BSL-3 or BSL-4 containment event

A uniform reporting structure does not reflect a meaningful tiered approach based on risk.

Requested action:

- Establish two levels of reporting: 1) Internal institutional record for nonreportable events, with optional de-identified submission to NBDSAC and 2) NIH report for events meeting defined NIH reporting thresholds, with enhanced fields incorporated only when warranted by the severity of the event.

- Assignment to an NIH reporting tier should determine the information provided confidentially to NIH and should not, by itself, require public posting.

Item 16: Incident Template - Other agency reporting is captured but coordination is not

Draft reference: "Has a report of this incident been made to other agencies? If so, indicate: CDC, USDA, FDA, EPA, OSHA."

Concern: The checkbox documents that another report occurred but does not address duplication, conflicting timelines, inconsistent definitions, or whether NIH will accept information already submitted to another federal agency. This creates the possibility of multiple reports containing similar information in different formats.

Requested action:

- Accept an equivalent report submitted to another federal oversight agency as satisfying NIH reporting requirements for overlapping elements and require only supplemental information that is uniquely necessary for NIH oversight.
- Coordinate definitions, timelines, and required data elements with other agencies to reduce duplicative oversight.

Item 17: Meeting Minutes Template - Shifts substantial local deliberation into a federal/public record

Draft reference: "Institutions must prepare IBC meeting minutes that ... document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities." Points to consider: "In general, the minutes should offer sufficient detail to serve as a record of all major points of discussion and the committee's rationale for decisions." "Key points made in discussion, motions of the committee, and whether those motions were approved should be documented."

Concern: Meeting minutes traditionally document committee action, but this template may transform detailed local technical deliberations into publicly available records used by NIH to judge compliance. Effective local oversight depends on committee members being able to discuss uncertainty openly without concern that preliminary statements will be interpreted externally as final findings.

Requested action:

- Require minutes to document the final risk assessment approval, committee decision, and approval conditions.
- A public-facing summary should state the general category of review, confirm that the required assessment occurred, and document the committee's final action without disclosing sensitive technical or operational details. Do not require a detailed public account of every technical discussion, preliminary concern, or alternative considered.

Item 18: Meeting Minutes Template - May unintentionally include general safety matters unrelated to covered biohazards

Draft reference: "All official business conducted at the IBC meeting should be documented using this template." Examples provided: "review of incidents, laboratory inspection reports, reports from safety personnel related to the safe conduct of research at the institution, personnel training, review of policies, etc."

Concern: These examples could encompass a broad range of institutional safety matters that are not necessarily connected to research involving biohazards covered by the draft policy. Laboratory inspections, training discussions, and reports from safety personnel frequently address chemical, physical, radiological, ergonomic, animal-handling, and general occupational hazards. Requiring these discussions to appear in the public IBC record could extend the effective scope of the template beyond biosafety oversight.

Requested action:

- Specify that only the portions of inspection reports, safety discussions, training matters, or policy reviews that materially relate to research subject to the draft policy must be included in the required minutes, and that other institutional safety business remains within the institution's existing oversight and recordkeeping processes.

Item 19: Meeting Minutes Template - Delegated review lacks defined eligibility and documentation standards

Draft reference: "Document all approvals granted by delegated review (may be attached to the minutes as a list). Note any specific issues discussed by the IBC as applicable."

Concern: The template does not identify which types of research may be approved through delegated review, who may act as a delegated reviewer, what expertise must be represented, how conflicts of interest must be managed, or whether the full IBC must subsequently ratify the action. Without standardized criteria, institutions may apply delegated review inconsistently, and the minutes may not provide enough information to show why a project was appropriate for review outside the convened committee.

Requested action:

- Define the minimum criteria for delegated review.
- Require the minutes to minimally identify the category of action, basis for delegated review, date of the decision, reviewer role or expertise, approval outcome, conditions imposed, and whether subsequent full-committee action is required.
- Do not require the public version to identify the individual reviewer by name.

Item 20: Meeting Minutes Template - Heavy administrative burden

Draft reference: "All official business conducted at the IBC meeting should be documented using this template." The template calls for documentation of institutional information, member attendance, quorum, conflicts, prior business, registrations, delegated reviews, risk assessments, training, occupational-health requirements, biosafety assignments, votes, incidents, inspections, public comments, and additional topics.

Concern: The expanded scope of the draft policy, combined with the level of detail required by the meeting minutes template, will substantially increase the administrative time and resources needed to support IBC oversight. Preparing detailed minutes is only one component of this burden. Institutions will also need to review the minutes for accuracy, evaluate information for privacy, proprietary, and security concerns, perform appropriate redactions, obtain IBC approval, maintain the records, and prepare and post a version suitable for public disclosure. As the number of activities requiring IBC oversight increases under the broader draft policy, these requirements will increase workload for IBC members, biosafety staff, PIs, administrative personnel, and other institutional functions supporting review and disclosure.

This additional administrative effort should be considered alongside NIH's goal of encouraging compliance. A framework that significantly increases the resources required to administer an IBC program may make voluntary adoption less attractive, even for organizations that otherwise support the draft policy's biosafety principles.

Requested action:

- Exempt non-NIH funded research from mandatory meeting minutes requirements and inclusion may be adopted as voluntary basis only.
- Streamline meeting-minute requirements and ensure that the required level of documentation is proportional to the risk and complexity of the research.
- Provide standardized templates, model language, clear redaction criteria, sample completed minutes, and guidance distinguishing information necessary for the institutional record from information necessary for public disclosure. These measures would reduce unnecessary administrative burden while preserving meaningful documentation, transparency, and biosafety oversight.

Item 21: Meeting Minutes Template - One document being used for three different purposes

Draft reference: "Institutions must prepare IBC meeting minutes that not only serve as the institution's record of the IBC's proceedings but also document for NIH and the public that the IBC is fulfilling its biosafety review and oversight responsibilities."

Concern: The template expects one document to function as the complete institutional record, evidence of compliance for NIH, and a public transparency document. These purposes require different levels of technical detail, confidentiality, and accessibility. Information necessary for the institution and NIH to evaluate a risk assessment may not be necessary or appropriate for unrestricted public release.

Requested action:

- Establish two related but distinct records: (1) complete institutional minutes available to NIH through a confidential oversight process when requested, and (2) a limited public-facing summary for research subject to the applicable public-disclosure requirement.
- Specify the public summary describes committee actions, principal hazards, final containment decisions, major safeguards, and approval conditions without reproducing sensitive technical or operational details.

- Agent-specific hazards, containment details, safeguards, technical deliberations, and sensitive conditions should remain in the complete institutional record.

Item 22: Meeting Minutes Template - Incident information may be unnecessarily duplicated

Draft reference: "Document any incidents (e.g., safety incidents, non-compliance issues); If none - state, 'nothing to report.'" The broader draft policy separately requires institutions to post incident reports publicly using the required incident-reporting template.

Concern: Requiring incident information in both publicly posted incident reports and publicly posted IBC meeting minutes creates duplicative documentation without a clear additional transparency benefit. The two records may contain different descriptions or redactions, particularly when the IBC discusses an incident before the investigation is finalized. This also increases the risk of premature disclosure and indirect identification of personnel.

Requested action:

- Permit meeting minutes to reference an incident by a unique identifier and document the IBC's review, determination, and resulting actions.
- Use the separate incident-reporting template as the authoritative institutional and NIH record of the event narrative and final findings. Meeting minutes should reference the report by a unique identifier and document only the IBC's review and resulting actions.
- Refer to Items 13-16 for the incident-reporting template.

Item 23: Meeting Minutes Template - Occupational health requirements

Draft reference: "Document any required occupational health requirements including, but not limited to: Vaccination requirements; Respiratory protection; Periodic review of any medical surveillance; Post-exposure response procedures."

Concern: Protocol-level occupational-health requirements can reveal information about expected exposure routes, agent consequences, specialized medical countermeasures, or the health requirements of a small and identifiable employee group. Detailed discussion may also create a risk of disclosing protected medical information.

Requested action:

- The public-facing summary should state only that applicable occupational-health requirements were reviewed and incorporated into the approval. Specific surveillance, vaccination, respiratory-protection, medical, and post-exposure requirements should remain in confidential institutional records.

Item 24: Clarify that BSO responsibilities may be fulfilled through oversight of qualified institutional programs and personnel

Draft reference: Section III-B, Biosafety Officer (BSO) Requirements and Duties

Concern: Section III-B is written as a single BSO personally responsible for conducting inspections, investigating incidents, and performing other operational functions. The draft policy does not recognize that these activities are often carried out by a multidisciplinary team or institutional program operating under the direct oversight of the BSO.

Requested action:

- Clarify that the BSO is responsible for the oversight, coordination, and effectiveness of these functions and that inspections, investigations, assessments, and related activities may be conducted by appropriately qualified personnel operating under the BSO's authority.
- Include the following language: "The BSO's duties may be carried out directly by the BSO or through the oversight, coordination, and review of appropriately qualified institutional personnel operating under the authority of the BSO."

Item 25: Clarify authority and responsibilities for biocontainment determinations

Draft reference: Section III-B, IBC Functions (independent risk assessment of required biocontainment levels and notification of the required biocontainment level); Section III-C, Responsibilities of the PI (initial risk assessment and selection of biocontainment levels).

Concern: The draft policy assigns containment-related risk assessment responsibilities to both the PI and the IBC but does not clearly identify who is responsible for proposing, evaluating, and approving the final biocontainment level. The requirement for both an initial PI risk assessment and an independent IBC risk assessment could be interpreted as requiring multiple independent evaluations of the same hazards without clarifying how disagreements should be resolved.

Requested action:

- Clarify that the PI is responsible for conducting the initial risk assessment and proposing the appropriate containment level and risk mitigation strategy.
- Clarify that the BSO may provide technical review and recommendations regarding containment, containment practices, and risk mitigation measures.
- Clarify that the IBC is responsible for reviewing the proposed containment level, considering the recommendations of the BSO and other subject matter experts as appropriate, and approving the final institutional biocontainment level.
- Specify how differing assessments among the PI, BSO, and IBC should be resolved and identify the institutional authority responsible for the final determination.

Item 26: Open-ended NIH interpretive authority and reliance on later guidance

Draft reference: Section III-D, Responsibilities of the NIH (bullets on "[p]romulgating requirements and guidance necessary to implement the NIH Biosafety Policy," "[i]nterpreting this Policy for cases in which the Policy does not specifically assign containment levels," restricting or withdrawing approval of Assurances, and verifying and directing institutional incident responses); Compliance and Enforcement ("including, but not

limited to"); Draft Incident Reporting Template ("additional measures to be taken as appropriate"); NOT-OD-26-112 (Risk Group classifications and other requirements to be provided as implementation resources)

Concerns:

- Requirements set outside the draft policy. The draft policy leaves key requirements to later guidance and NIH interpretation. These include Risk Group classifications, containment and training requirements for certain work, and containment for agents the draft policy does not assign. Institutions are asked to comment on a draft policy whose operative details are not yet defined, and those details could change without further public input.
- Standards defined after the fact. Several terms that determine what is reportable and what counts as compliance are undefined, including "significant risk to human health," "incident," "any compliance violations," and "timely manner." NIH's authority to interpret the draft policy and to verify that an institution's response "is appropriate" would give those terms their practical meaning case by case, after events occur.
- Interpretation, enforcement, and standard-setting in one party. NIH issues guidance, interprets gaps, judges compliance, and decides on enforcement, with no stated appeal path, deadline, or requirement to publish its interpretations. Institutions cannot know in advance what will satisfy NIH.
- Compliance exposure. Compliance is a term and condition of award, and enforcement can affect future funding. An institution acting in good faith on a reasonable reading could face action if NIH later reads the draft policy differently.
- Open-ended consequences. "Including, but not limited to" and "as appropriate" leave the range of NIH's required actions and enforcement responses undefined.
- Inconsistent application. Without published interpretations, NIH could treat similar facts differently across institutions, and institutions could not learn from one another's determinations.

Requested action:

- Place in the draft policy text, not in later guidance, the elements that determine scope, review tier, containment, reporting, and compliance. These include Risk Group classifications and the definitions listed in the related items.
- Provide for public notice and comment before implementation resources or guidance that create or change requirements take effect, and state that such guidance is not binding unless it has gone through that process.
- Require NIH to publish its interpretations and determinations of general applicability, and to give written reasons for individual determinations.
- Provide a good-faith compliance provision: an institution that acts on a reasonable, documented interpretation of the draft policy or of published NIH guidance will not face enforcement for that interpretation.
- Establish a process for institutions to request a written interpretation from NIH, with a response deadline, and a reconsideration and appeal path for adverse determinations.
- Provide advance notice and a reasonable transition period when NIH guidance changes requirements, and limit retroactive application.

- Replace "including, but not limited to" and "as appropriate" with defined lists of possible actions and the circumstances for each.

Item 27: "Any compliance violations at any BSL/ABSL" and the lack of reporting guidance

Draft reference: Section III-B, IBC Functions (reportable incidents include "Any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approval, or failure to obtain NIH approval for lowering biocontainment for research, when required"); Draft Incident Reporting Template

Concern:

- Undefined scope. The draft policy does not say whether "compliance violations" means violations of the draft policy only, or also violations of requirements enforced by other oversight bodies, such as the Federal Select Agent Program, OSHA, other federal agencies, or state and local authorities. The two examples given are illustrative, not limiting.
- Duplicative reporting. If the broader reading applies, the same event would be reported to multiple bodies with different timelines, definitions and content, and then posted publicly. That duplicates existing oversight and risks inconsistent records of the same event.
- No reporting guidance. The Incident Reporting Template does not appear to include a section or instructions specific to compliance violations. Its fields are built around physical events such as exposures, spills and equipment failures. Institutions therefore have no guidance on what to submit for a compliance event, and the template does not fit one.
- Disproportionate treatment of administrative lapses. Because the term is undefined and applies at any biosafety level, an administrative lapse, such as a late IBC renewal under the three-year approval cycle, could carry the same 24-hour clock and public posting as an exposure event.

Requested action:

- Limit this category to violations of the policy, and enumerate the specific violations that are reportable.
- State that violations reportable to and handled by another oversight body (for example, the Federal Select Agent Program or OSHA) are not separately reportable to NIH, or accept the other body's report as satisfying NIH's requirement.
- Add compliance-violation fields and instructions to the Incident Reporting Template, or issue separate reporting guidance.
- Distinguish administrative lapses from events that pose a risk to human health, provide a cure period for administrative lapses, and exclude them from the 24-hour notification and from public posting.

Item 28: IBC meeting minutes template creates serious security risks to personnel, institutions and national interests

Draft reference: Section III-B, IBC Functions (IBC meeting minutes prepared using the required template and posted on a public-facing webpage); Draft IBC Meeting Minutes Template and Points to Consider ("The names of IBC members may not be redacted from the minutes"; "The names of the PIs may not be redacted from minutes"; information such as "names of IBC members and PIs, biological agents used in research, including Select Agents, grant numbers ... may not be redacted from the IBC minutes"; redaction permitted only for information "where disclosure would directly compromise institutional or national security")

Concern:

- A roadmap to people and programs. Under the template, each set of posted minutes would publicly link named PIs and IBC members to:
    - their institution, city and state
    - the specific agents and toxins they work with, including Select Agents
    - the animal models used
    - the containment level and safeguards in place
    - the training and occupational health requirements that apply to them
- The template also calls for the meeting date, start and end times, whether the meeting is in person or virtual, the platform used, and the date, time and platform of the next meeting. Together, these elements identify who does the work, what the work is, where it happens, and when and how the oversight committee meets.
- Targeting by extremist groups. Research that uses animals, and particularly research with nonhuman primates, has long been a focus of animal rights extremism. Researchers, staff and their families have faced harassment, intimidation, threats and attacks. The template asks for animal models, animal procedures, animal-handling training (including "primate safety"), and the names of the investigators and committee members involved, and it prohibits redacting those names. Publicly posting this information turns a compliance record into a target list. It exposes individuals and their families to harassment and violence, and it exposes institutions to disruption and property damage.
- Collection by foreign competitors and adversaries. NIH already requires public posting of approved IBC meeting minutes for research subject to the current 2024 NIH Guidelines. The proposed policy would extend that framework beyond recombinant or synthetic nucleic acid research to a broader range of biological agents, toxins, prions, genetically modified organisms, and other covered biohazards, while the required template would standardize the disclosure of agents, modifications, methods, safeguards, personnel, and unpublished supporting information. This expanded and standardized record could be aggregated at scale by foreign governments and competitors to identify emerging U.S. research directions, institutional capabilities, and sensitive technical information before publication, patenting, or commercialization.
- Expanded dual-use information hazard. Although NIH already requires public posting of IBC minutes, the proposed policy would broaden the covered research and standardize disclosure of agent characteristics, genetic modifications, attenuation methods, experimental manipulations, risk-mitigation measures, and other technical details. Individual disclosures may appear limited, but their aggregation across meetings and institutions could reveal both the biological hazards under study and the controls used to manage them, increasing the potential for misuse.
- Additional risk: disclosure of vulnerabilities. The template asks for laboratory inspection results, deficiencies and their correction, incidents and follow-up, conditional approvals (for example, biological safety cabinet certification), building maintenance, and waste-handling practices that differ from institutional policy. Publicly listing where controls were found deficient tells an adversary where an institution may be weakest.
- Additional risk: social engineering and cyber targeting. Names, roles and expertise of committee members and investigators, together with meeting schedules, virtual platforms, and descriptions of

institutional IT systems under development, support targeted phishing, impersonation, and attempts to access meetings or institutional systems.

- Additional risk: insider and access risk. Identifying which staff are trained for high-containment work, which personnel require specific vaccinations, and which individuals have access to particular agents tells a malicious actor whom to approach, pressure or recruit.
- Additional risk: aggregation at national scale. One institution's minutes may seem harmless in isolation. Minutes from every covered institution, posted in a standard format and kept for at least five years, form a national dataset of where agents are held and who works with them. Automated and AI-assisted tools make that dataset easy to compile, search and map. Copies remain in web archives and third-party collections after the institution removes the original. The redaction standard does not account for this aggregation, and it treats information as public if any piece of it appears elsewhere.
- Additional risk: inconsistency with Select Agent protections. Information about who possesses Select Agents and where is treated as security-sensitive under the Federal Select Agent Program. The template expressly prohibits redacting Select Agent identities from public minutes. Because entities must comply with both, the template creates a direct conflict with existing federal security practice.
- Additional risk: weaker oversight and workforce. Non-affiliated community members serve on IBCs as volunteers. Publicly listing their names alongside high-risk research will discourage qualified people from serving, and may discourage scientists and staff from working in high-consequence research fields. That weakens the oversight the draft policy seeks to strengthen.
- Redaction standard is too narrow to address these risks. Redaction is limited to information whose disclosure would "directly compromise" security. Most of the risks above come from aggregation, indirect identification and cumulative exposure, which "directly" does not capture. NIH itself recognizes that "specific facility addresses may be security sensitive," but it requires the same institutions to publish the people, agents and practices inside those facilities.
- Existing posting is not a reason to expand content. Public posting of minutes already applies to meetings on or after June 1, 2025. The mandatory template, its content requirements, and its prohibitions on redaction would substantially increase the sensitivity of what is posted. Because posting is already in place, these content requirements need to be reconsidered before they are finalized.

<u>Requested action:</u>

- Remove the prohibitions on redacting the names of IBC members and PIs. Allow institutions to identify members by role and expertise in public minutes, and to provide names to NIH.
- Remove the prohibition on redacting biological agents and Select Agents. Allow agent identities to be described by risk group or general category in public minutes.
- Replace "directly compromise institutional or national security" with a standard that allows redaction of information that could reasonably be expected to endanger personnel, facilities or security, individually or in combination with other information.
- Do not require public posting of meeting times, meeting format or platform, next-meeting details, inspection deficiencies, incident details, occupational health requirements, or references to unpublished data.

- Limit public minutes to a summary of committee actions and confirmation that required reviews occurred. Retain full minutes at the institution and provide them to NIH on request.
- Exempt minutes for research involving Select Agents, BSL-3/ABSL-3 or BSL-4/ABSL-4 work, and nonhuman primates from public posting, and provide them to NIH confidentially.
- Before finalizing the template, conduct a formal security review with federal law enforcement, intelligence and research security partners, including an assessment of aggregation and automated collection. Publish the results.
- Align the template with Federal Select Agent Program information protections and with federal research security policy.

Item 29: IBC meeting minutes template may require public release of export-controlled information and controlled unclassified information

Draft reference: Section III-B, IBC Functions (IBC meeting minutes prepared using the required template and posted on a public-facing webpage); Draft IBC Meeting Minutes Template and Points to Consider (Project Overview to include agent name and characteristics, sources and nature of nucleic acid sequences, modifications made to attenuate agents or render them replication-incompetent, supporting published or unpublished data, and experimental manipulations; redaction limited to proprietary or private information and information "where disclosure would directly compromise institutional or national security"; names of PIs, IBC members, and biological agents, including Select Agents, "may not be redacted")

Concern:

- Export-controlled technology. Federal export control regulations control certain biological agents and toxins, along with certain technology for their development or production. The template's Project Overview, Risk Assessment and Biosafety Level fields call for the kind of technical detail that can fall within those controls. Examples include genetic modifications, attenuation methods, sequence sources, agent characteristics and experimental procedures. Posting that information on a public website could be an unauthorized release of controlled technology. Once posted, it becomes available to anyone, including foreign persons and restricted parties, and cannot be retrieved.
- Fundamental research does not cover all covered work. Much academic research falls under the fundamental research exclusion from export controls. Contract and sponsored research often does not, particularly where the sponsor restricts publication or dissemination. The draft policy's reach extends to non-NIH-funded work (see Item 7). Under it, institutions would have to publicly post minutes for research that is export-controlled because it is not fundamental research.
- Controlled unclassified information (CUI). Research performed under federal contracts may involve CUI, which must be safeguarded and may not be publicly released unless the designating agency has decontrolled it. Institutions are not authorized to decontrol CUI. A minutes template that requires public summaries of such research, and prohibits redacting key elements, places institutions in direct conflict with their contractual and regulatory obligations to protect CUI.
- The redaction standard does not cover either category. The template permits redaction of proprietary or private information and information whose disclosure would "directly compromise institutional or national security." It does not mention export-controlled information or CUI. Neither category is

necessarily "private" or "proprietary," and neither requires showing a direct security compromise. As written, institutions have no clear authority to redact information they are legally required to protect.

- Conflicting legal obligations. Institutions cannot satisfy both requirements. Complying with the template could violate export control or CUI requirements, and withholding the information could be treated as noncompliance with the draft policy and affect NIH funding. The draft policy provides no mechanism to resolve the conflict.
- Deemed exports within the IBC itself. Before anything is posted, IBC review places technical information in front of all committee members, including non-affiliated community members. If a member is a foreign person, sharing export-controlled technology with them may itself require an export license. The draft policy's membership and review requirements do not account for this.
- Lasting loss of control. Information released publicly is collected, archived and redistributed by third parties. A later correction, redaction or removal does not undo the release.

Requested action:

- State expressly that nothing in the draft policy, the meeting minutes template or the incident reporting template requires public disclosure of export-controlled information or controlled unclassified information.
- Add export-controlled information, CUI, and information restricted by a federal sponsor or contract to the categories that institutions may redact or withhold, without requiring a showing of direct security compromise.
- For research that is not fundamental research, or that involves export-controlled information or CUI, permit minutes to record only that the review occurred and the approval decision, and provide full minutes to NIH through an appropriately controlled channel.
- Allow IBC review of export-controlled or CUI-related research to be conducted by members eligible to receive that information, and state that this satisfies the draft policy's membership and review requirements.
- Coordinate the templates and redaction guidance with the Departments of Commerce and State and the CUI Executive Agent before the draft policy is finalized.

Item 30: Preserve influenza-specific safeguards against unintended genomic reassortment

Draft reference: Section IV, experiments involving influenza viruses; current NIH Guidelines, Section III-D-7, Experiments Involving Influenza Viruses.

Concern: The draft policy assigns containment for influenza research according to the Risk Group of the virus contributing the majority of genomic segments and establishes enhanced containment for certain 1918 H1N1, human H2N2, and HPAI H5N1 experiments. However, it does not expressly require institutions to evaluate and control the risk of unintended genomic reassortment when different influenza strains are studied concurrently or sequentially in shared rooms, equipment, animal spaces, or supporting systems.

Influenza viruses possess segmented genomes, and concurrent exposure to different strains can create conditions for reassortment. Available federal guidance, such as the BMBL, does not comprehensively address

temporal and spatial separation for concurrent or sequential recombinant or synthetic influenza research. USDA APHIS guidance addresses concurrent HPAIV and 1918 influenza studies, but NIH should establish a broader framework for identifying and mitigating unintended reassortment risks involving other consequential strain combinations. This gap illustrates why Risk Group classification alone cannot replace a protocol-specific assessment of the resulting agent, concurrent research activities, shared spaces and equipment, and credible pathways for unintended reassortment.

Requested action:

- Retain explicit influenza-specific safeguards requiring IBC assessment of unintended genomic reassortment during recombinant, synthetic, reverse-genetics, and reassortant influenza research. The assessment should address concurrent and sequential work, temporal or spatial separation, shared rooms, equipment and animal spaces, validated decontamination between activities, and documented clearance before another influenza strain is introduced.
- Publish influenza-specific implementation guidance identifying the existing safeguards that will be retained, modified, relocated, or discontinued and establishing minimum controls for strain combinations capable of producing a more pathogenic, transmissible, or otherwise consequential reassortant.

Item 31: Retain a stable and transparent Risk Group classification resource

Draft reference: Section IV, Categories of Oversight for Research Based on Risk; Section V, Risk Assessment and Mitigation for Research Involving Biohazards; NOT-OD-26-112 and the Draft Policy Table of Changes regarding Risk Group classifications as implementation resources.

Concern: The draft policy relies on Risk Groups to determine oversight pathways and inform risk assessment but does not retain the agent classification lists contained in the current NIH Guidelines. Moving these classifications to a separate implementation resource creates uncertainty regarding where the authoritative classifications will reside, how changes will be reviewed and communicated, and whether classifications could change without stakeholder notice.

Risk Groups provide an important starting point for biological risk assessment, but they do not independently determine the appropriate containment level for a specific protocol. Final BSL or ABSL determinations must also consider the characteristics of the resulting agent, genetic modifications, experimental procedures, routes of exposure, scale, aerosol potential, animal work, and available safeguards.

Requested action:

- Retain the Risk Group classification lists in the draft policy or in a formally controlled, publicly accessible implementation resource that identifies the authoritative classification, revision date, supporting rationale, and effective date of each material change.
- Establish a transparent process for modifying Risk Group classifications that includes scientific review, advance notice to affected institutions, publication of the basis for the change, and a reasonable implementation period.

- Clarify that Risk Group classification is a starting point for protocol-specific risk assessment and does not automatically determine the final BSL or ABSL, which should be approved by the IBC based on the agent, modifications, procedures, and other relevant risk factors.

Battelle appreciates the opportunity to provide comments on the Draft NIH Biosafety Policy for Research Involving Biohazards. These recommendations are intended to improve regulatory clarity, preserve risk-based institutional oversight, coordinate NIH requirements with existing federal frameworks, protect sensitive research and personnel information, and ensure that transparency measures do not displace the preventive controls necessary for effective biosafety.

Battelle respectfully requests NIH's consideration of these comments as it develops the final policy, templates, and implementation materials.

273. The University of Vermont

I am responding: On behalf of an organization

Name: Sara Cahan

Name of Organization: The University of Vermont

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Fundamental and clinical biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: UVM_NIH_Biosafety-hazard_draft_policy_comment.pdf

Subject: Comments on Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Introduction

The University of Vermont (UVM) appreciates the opportunity to respond to the Request for Comment regarding the Draft NIH Biosafety Policy for Research Involving Biohazards, the Draft Incident Reporting Template, and the Draft Meeting Minutes Template.

UVM is a public R1 research institution conducting a diverse portfolio of biomedical, translational, agricultural, environmental, and public health research supported by federal, state, foundation, and industry sponsors. The University's research activities span basic, applied, and clinical investigations and include collaborations with academic, government, healthcare, and industry partners. Accordingly, UVM maintains a comprehensive research oversight framework designed to support scientific discovery, ensure regulatory compliance, manage biological and research-related risks, and maintain public trust.

We share the NIH's commitment to the modernization of biosafety oversight in research and welcome clearer authority, stronger institutional standing, and a well-defined mandate that allows risk-based management of all biological hazards.

UVM believes the proposed policy would benefit from further refinement to improve clarity, reduce interpretive ambiguity, and reinforce the principle of risk-based oversight that underpins effective biosafety governance. Below, we outline in more detail the basis for our concerns and recommended remedies, organized by the relevant section(s) of the draft policy.

Scope of the NIH Guidelines
Sections I- A to 1-D
UVM supports the proposal's emphasis on focusing IBC resources on higher-risk activities. However, without defined risk categories, review thresholds, and objective decision criteria, institutions may apply the framework inconsistently, potentially increasing oversight burden for lower-risk research and reducing consistency across the research enterprise.

Impact: UVM generally supports the expanded scope because it aligns with the University's existing integrated approach to biosafety oversight. However, absent clear risk-based guidance, the proposal may substantially increase institutional administrative workload for activities presenting minimal biosafety risk. The impact is therefore positive in concept but potentially negative operationally.

Recommendation: ***To enable effective and efficient compliance with the proposed framework, UVM recommends providing more detailed guidance regarding risk categories, exclusions, and review thresholds*****.**

Institutional Submissions to NIH

Section IV-B-2-a
Section IV-B-2-c
UVM supports replacing annual roster submissions with a four-year institutional assurance model, which shifts oversight to functional elements of the institutional biosafety program rather than administrative reporting. However, the proposal provides limited detail regarding assurance review criteria, approval timelines, updates between submission cycles, and the consequences of material changes to institutional programs.

Impact: This change is expected to have a generally positive impact by reducing recurring administrative reporting requirements and allowing greater focus on substantive program elements. The benefits, however, will depend on clear expectations regarding assurance review criteria, submission requirements, amendment procedures, and the management of institutional program changes.

Recommendation: ***To avoid uncertainty over compliance requirements, UVM recommends that the policy provide sufficient detail to operationally guide institutional activities*****.** Having clear expectations would improve predictability, reduce uncertainty, and support consistent implementation across the research enterprise.

IBC Functions: Incident Reporting

Section IV-B-2-b-(7)
Appendix G-II-B-2-k
Appendix G-II-C-2-q
Appendix G-II-D-2-k
UVM is concerned that the proposed incident reporting provisions expand reportable events to include administrative and procedural issues that have been, historically, appropriately managed through existing institutional oversight processes. While supporting transparency, UVM believes the proposed public disclosure requirements may inadvertently discourage reporting of near misses and minor incidents that are essential to a strong culture of safety.

UVM is also concerned that the proposed reporting framework may create substantial intra-institutional and inter-institutional overlap, resulting in increased administrative

burden, duplicative effort, and unclear lines of responsibility. Within institutions, a single event may require parallel review and reporting through multiple oversight functions, including biosafety, human subjects protections, animal care and use, occupational health and safety, environmental health and safety, compliance, and research administration offices. Across institutions, collaborative research arrangements may require multiple organizations to independently assess, investigate, document, and report substantially the same event, creating redundant processes and increasing the potential for inconsistent reporting.

These overlapping requirements may also adversely affect research collaboration. Effective multi-institutional research depends upon clearly defined responsibilities, efficient information sharing, and streamlined oversight processes. A reporting framework that generates duplicative reviews, overlapping reporting obligations, or multiple requests for the same information may increase administrative complexity and create barriers to scientific collaboration without providing a commensurate increase in biosafety protections.

UVM is additionally concerned about the potential impact on public-private research partnerships. Corporate research partners may be particularly sensitive to reporting requirements that could result in public scrutiny of preliminary investigations, minor incidents, or events that are ultimately determined to pose minimal biosafety risk. Absent clear risk-based reporting thresholds and appropriate protections of sensitive information, expanded reporting obligations may discourage industry participation in collaborative research and increase the administrative and legal complexity of such partnerships.

Impact: This provision is likely to have the most significant operational impact. Expanded reporting requirements may duplicate existing obligations across biosafety, human subjects, animal care and use, occupational health, environmental health and safety, compliance, and research administration programs. Without clear coordination mechanisms and risk-based reporting thresholds, the proposal may increase administrative burden, complicate multi-institutional collaborations, and discourage industry partnerships without a corresponding improvement in biosafety outcomes.

Recommendation: ***UVM recommends limiting public reporting to incidents with significant biosafety, biosecurity, or public health implications while preserving institutional mechanisms for managing lower-risk events.*** UVM offers as examples the NASA Aviation Safety Reporting System (ASRS) and the National Fire Fighter Near-Miss Reporting System; two nationally recognized incident and near-miss reporting systems that emphasize confidentiality, learning, trend analysis, and system improvement rather than

punitive or publicly scrutinized reporting frameworks, thereby encouraging candid reporting and broader participation.

Categories of Research (Lowering of Containment)

Section III-A (Applicable Sections)
Section IV-C-1-b
Appendices G, K, and L
UVM is concerned that centralized NIH approval of all initial RG3 and RG4 containment-reduction requests could create a regulatory bottleneck while providing limited additional safety benefit where robust risk assessment and containment data already exist.

The practical challenge is that only a small fraction of projects are likely to present true biosafety concerns, while a far larger number may require preliminary screening to demonstrate that they do not. The resulting requirement to evaluate all proposed and ongoing life sciences research could create a significant new compliance obligation. Institutions would need to invest substantial resources in administration, training, screening, documentation, and review, including for funding proposals that ultimately are not awarded and research projects that never come to fruition.

Impact: Potentially negative. Even though only a small fraction of projects request or require containment-reduction, requiring centralized approval may introduce delays, create new administrative obligations, and require institutions to devote substantial resources to evaluating and documenting activities that ultimately do not warrant additional biosafety oversight.

Recommendation: ***The proposal should include clear approval standards, defined review timelines, and a transparent process for relying on prior NIH determinations to ensure consistent, predictable, and efficient oversight*.**

Delegated Review of Research

Section III-D
Section III-E

UVM notes the proposed delegation authority may unintentionally create inconsistencies in biosafety oversight absent clearly defined eligibility standards and review expectations.

Several proposed categories encompass a very wide spectrum of risk (toxins, viral vectors) and the framework provides limited guidance regarding when delegated review is appropriate versus when full IBC deliberation is warranted.

Impact: Potentially positive. When accompanied by clear eligibility standards and safeguards, delegated review could improve efficiency, reduce unnecessary committee workload, and better align review intensity with actual biosafety risk while preserving oversight quality.

Recommendation: ***The final guidance should establish objective biosafety characteristics that trigger IBC review, minimum reviewer qualifications, documentation standards, and escalation criteria, rather than relying primarily on broad product categories.*** This will promote predictable and consistent oversight nationwide without diminishing the rigor, transparency, or consistency of institutional biosafety oversight.

Clinical Research

Section III-C-1

While UVM supports biosafety oversight of clinical research involving replicating, integrating, shedding, or RG2-or-higher biological agents, the proposed categories require further clarification. Several terms remain broadly defined and may encompass activities with substantially different risk profiles.

Impact: Generally positive if objective review criteria and clear boundaries between biosafety and existing human-subjects oversight functions are established. Absent such clarity, institutions may experience duplicative reviews and inconsistent application of requirements.

Recommendation: ***The final guidance should establish objective risk-based criteria, examples, and review thresholds to promote consistent determinations regarding when IBC review is warranted and to reduce variability between institutions.***

Research Involving Genetically Modified Plants

Section III-D-5
Section III-E-2
Appendix L

UVM supports focusing the proposed Biosafety Policy on activities presenting direct human health risks. However, excluding genetically modified plants from this policy does not mean that they lack oversight altogether, which may not be clear without qualifying language.

Impact: Generally positive. The proposed approach appropriately focuses biosafety oversight on human health risks while allowing institutions to continue applying environmental, agricultural, and other relevant oversight frameworks where warranted.

Recommendation: ***The exclusion of genetically modified plants and plant pathogens that do not cause human disease should be accompanied by clear acknowledgment that such research may still warrant review under other institutional, environmental, agricultural, or regulatory oversight frameworks.***

Required Documentation

Section IV-B-2-b-(7) (IBC)
Section IV-B-7-b (PI submissions to NIH OSP)
UVM supports the objective of improving consistency and information quality through standardized documentation; however, mandatory templates may require manual handling of information already maintained within institutional electronic systems. Institutions utilizing electronic research compliance systems will have to export, reformat, or manually transfer information into mandated templates solely to satisfy formatting requirements, increasing both administrative burden and the risk of human error.

Impact: Strongly negative. Institutions with mature electronic compliance systems may be required to create manual workarounds to satisfy formatting requirements despite already maintaining the required information electronically. A data-element approach would better support consistency while preserving efficiency and reducing opportunities for error.

Recommendation: ***The policy would be strengthened by requiring a standardized set of data elements rather than prescribed document formats.***

Additional Comments

The implementation timeline for these changes remains unclear. The proposal represents a substantial expansion of institutional biosafety oversight responsibilities and cannot reasonably be implemented within a short transition period. Most institutions would require at least 12 to 18 months, and potentially longer, to revise policies and procedures, establish new review pathways, configure electronic compliance systems, recruit and train

personnel, educate investigators, and achieve sustainable compliance with the proposed requirements.

The cumulative impact of these changes on both Institutional Biosafety Committees (IBCs) and institutional administrative offices is likely to be significant. The expanded scope of oversight would increase demands associated with protocol intake and review, pre-award compliance assessments, investigator training, inspections, incident management, recordkeeping, post-approval monitoring, and regulatory reporting. While the proposal appropriately elevates the importance of biosafety oversight, successful implementation will require corresponding investments in personnel, expertise, information systems, and administrative infrastructure.

UVM is particularly concerned that these expanded responsibilities are proposed without accompanying risk stratification criteria, implementation guidance, or a defined transition framework. As a result, institutions may be required to commit substantial resources before the scope of required oversight activities can be consistently interpreted and applied. Greater clarity regarding risk categories, review expectations, implementation milestones, and resource assumptions would improve consistency across institutions and facilitate more effective adoption of the policy.

Without additional guidance and a realistic implementation timeline, institutions may face significant compliance burdens without the desired corresponding improvement in biosafety.

Overall Impact: UVM supports the policy's underlying goals and recognizes that many aspects of the proposal are consistent with practices already employed within mature institutional biosafety programs. However, as currently drafted, the proposal would likely have a net negative operational impact due to expanded administrative burden, overlapping reporting requirements, implementation costs, and the absence of sufficiently defined risk-stratification criteria. Additional guidance, flexibility, and implementation planning would improve both effectiveness and institutional sustainability.

Conclusion

UVM appreciates the opportunity to contribute to this important discussion. These comments are submitted in the spirit of partnership, scientific advancement, and stewardship of public trust. We share the goal of a biosafety framework that protects communities, supports responsible institutional oversight, and enables continued innovation and discovery. We respectfully encourage the adoption of a final policy that is clear, risk-informed, sustainable, and practical to implement, while supporting an evolving research enterprise that advances discovery, safeguards communities, strengthens

institutional responsibility, and promotes the responsible progress of science for years to come.

274. University of North Carolina Charlotte

I am responding: On behalf of an organization

Name: Cathy Moore

Name of Organization: University of North Carolina Charlotte

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Clarification is requested regarding the explicit exclusion of plants from the scope of Section II. Institutional members seek guidance on whether plant research will be subject to a separate companion federal oversight policy, or if this creates a regulatory gap. Further clarification is needed on how the policy governs toxins expressed within plant systems. Under Section II, toxins are explicitly within the scope, while plants are excluded, creating ambiguity over whether toxin expression in plant tissue is considered out of scope due to the plant host, or in scope due to the toxin itself.

The proposed definition of genetic modification in Section II includes “stable alterations into the genome by passaging…” Operational guidance is requested to distinguish routine subculturing from passaging that triggers policy oversight. Institutional members seek clarity on whether routine passaging of organisms triggers review, or if oversight applies strictly to deliberate experimental evolution protocols.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Concerns have been raised regarding the burden placed on environmental sampling and surveillance research (e.g. soil, water, or field sampling), where the risk group or agent identified is inherently unknown or may yield novel or emerging agents. Clarification is requested on whether routine environmental sampling automatically triggers the highest tier of review by both the NIH and IBC. Requiring the highest tier federal review for sampling unknown environmental microbes without a pre-determined risk group creates significant administrative bottlenecks and potential delays for research and training programs.

Section II defines a novel agent or organism as one “not existing in nature, deliberately designed…”. However, the policy lacks operational guidance on the degree of genetic divergence required for a modified organism to cross the threshold from a routine genetic modification to a novel agent. Institutional Biosafety Committees will need clear criteria for what constitutes a novel agent. Without clear boundaries, institutions may default to over-classifying minor genetic variants as novel agents, triggering the highest tier of oversight by both the NIH and IBC, delaying routine research.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Concerns were raised regarding the requirement to publish incident reports directly on public-facing institutional websites and what redactions are allowable. Public exposure with identifying details may create a reporting deterrent, inadvertently discouraging researchers from coming forward to report incidents. Institutional members recommend that incident data and reporting templates be submitted to and maintained within a centralized NIH database (such as the proposed National Biosafety Data and Safety Analysis Center) in a de-identified or restricted format, rather than hosted on public institutional websites.

6. Other feedback relevant to this resource: N/A

275. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: a. Definitions

For the scope of the policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:
1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above.

The policy should clarify if this includes the following:
1. Bloodborne pathogens (BBPs): Infectious microorganisms present in human blood and other potentially infectious materials that are capable of causing disease in humans.
2. Environmental samples: Soil, water, air, and other environmental samples that may contain infectious microorganisms or other potentially infectious materials.
3. Materials containing or potentially containing the above: Bloodborne pathogen materials and environmental samples containing agents or materials identified in categories 1 and 2, including materials containing combinations of these hazards.

A clear and comprehensive definition would help institutions consistently determine which research activities fall within the policy's scope.
Overall, the policy could improve on the consistency of terms and definitions.

b. Research Involving Plants

If research involving wild-type and genetically modified plants is not covered by this policy, will NIH clarify whether USDA/APHIS will establish a separate policy or oversight framework for this type of research?

c. Research Conducted in Clinical Settings

Can the Institutional Biosafety Committee (IBC) and Biological Safety Officer (BSO) establish appropriate IBC review and survey requirements for research conducted in clinical settings? Such research may involve different physical environments, workflows, and risk mitigation practices than those used in traditional BSL laboratories. The policy should allow sufficient flexibility to accommodate these differences while maintaining appropriate biosafety oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I would request clarification on the topics below:

a. Research Requiring NIH and IBC Approval Prior to Initiation

1. Will NIH publish the outcomes of its reviews for higher-risk research involving emerging, novel, or zoonotic agents for which a Risk Group (RG) classification or minimum containment level is not currently established in the Biosafety in Microbiological and Biomedical Laboratories (BMBL)?
2. If NIH establishes a determination or containment recommendation through its review process and subsequently publishes that information, would institutions still be required to submit individual protocols for NIH review, or would the published determination eliminate the need for additional NIH review?

b. Research Requiring IBC Review and Approval Prior to Initiation

For research involving toxins listed as Select Agents, does the proposed oversight requirement apply only to quantities exceeding the applicable exemption limits, or would IBC review be required regardless of the quantity?

c. Research Requiring Review and Approval Prior to Initiation That May Be Delegated to an Individual or Subgroup of IBC Members

1. Minor amendments: How will “minor amendment” be defined? For example, would a minor amendment be limited to changes that do not alter the risk assessment or required containment level?
2. IBC membership: Must the individual or subgroup conducting the delegated review consist of voting members of the IBC?
3. Reporting to the full IBC: What is the expectation for an item to be “reported in full” to the IBC? Would written reporting to the full committee satisfy this requirement, or is discussion during the convened IBC meeting expected?

3. Continued utility of Risk Groups: I agree that Risk Group classifications remain an important foundation for biosafety risk assessments and continue to have value under the proposed policy.

However, it would be extremely beneficial to biosafety professionals if the RG classifications were expanded, made publicly accessible, and maintained as a dynamic resource. If Appendix B is no longer available and the BMBL is limited in the agents it assigns risk groups to, then biosafety professionals need a resource that can provide current RG classifications to be the starting point for risk assessments,

which review the agent, practices, and training to assign the BSL for containment and facility requirements. NIH could consider establishing a publicly available list that is updated in a timely manner as NIH completes reviews of emerging, novel, and zoonotic agents. Such a resource would provide institutions with greater consistency and transparency when conducting risk assessments and determining appropriate containment measures.

Risk Group classifications do not equate to Biological Safety Level (BSL). The BMBL provides standard and special microbiological practices, safety equipment, and laboratory facility requirements for each BSL, but it is the institution's IBC that establishes the BSL based on the research risk assessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: IBC Meeting Minutes

a. Documentation of IBC Member Expertise
Requiring IBC meeting minutes to document individual members' expertise may be duplicative, as this information is already included in the institution's publicly available IBC roster. Consider allowing the publicly available roster to satisfy this requirement, provided that the roster sufficiently describes the expertise represented on the committee.

b. Project Descriptions
Principal Investigators (PIs) may have concerns regarding the level of detail required in project overviews included in publicly available IBC meeting minutes. The policy should clarify the expected level of detail while ensuring that proprietary, confidential, or otherwise sensitive information is appropriately protected.

c. Incidents and Inspection Surveys
Documentation of incidents and inspection surveys in publicly available IBC meeting minutes should not contain personally identifiable information. Rather, summaries should provide sufficient information to describe the nature of the event, the associated risk, and the corrective actions taken without identifying individual personnel.

Incident Reporting

Posting incident reports on a public-facing website using the proposed reporting template may present several challenges to consider.

a. Potential Reduction in Reporting
Public disclosure of incident reports may discourage reporting because personnel and institutions could be concerned about the lack of confidentiality. This could result in underreporting of incidents and near misses, ultimately reducing the value of the reporting system as a biosafety learning and prevention tool.

b. HIPAA and Other Confidentiality Requirements
Incident reports may contain information that requires redaction to comply with HIPAA or other

applicable privacy and confidentiality requirements. The policy should clearly distinguish between information that must be submitted to NIH and information that is appropriate for public disclosure.

c. Scope of Incidents Requiring Reporting
The definition of a reportable incident should focus on events relevant to biosafety and biosecurity risks, such as:
• Exposure to a biohazard;
• Release or potential release of a biohazard;
• Laboratory equipment failures that result in or could result in exposure or release; and
• Significant near misses involving biohazardous materials.

Routine occupational safety incidents, such as slips, trips, and falls unrelated to a biohazard, should not be included in the proposed biosafety incident reporting framework.

6. Other feedback relevant to this resource: The proposed three-year renewal cycle is likely to significantly increase the administrative burden on both Principal Investigators and IBCs. Institutions currently operating under a five-year renewal cycle would experience a substantial increase in the frequency of protocol renewals, potentially doubling the IBC workload associated with renewals.

In addition, the primary administrative and technical resource for biosafety review and may require additional staffing or other resources to support the increased workload.

I encourage NIH to consider the administrative implications of the proposed three-year renewal cycle and evaluate whether a risk-based or tiered renewal schedule could achieve the desired level of oversight while minimizing unnecessary administrative burden. A risk-based approach could allow more frequent review for higher-risk research while permitting longer renewal intervals for lower-risk activities that have demonstrated effective oversight and compliance.

276. Brett Haltiwanger

I am responding: On behalf of myself

Name: Brett Haltiwanger

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The current draft states that it covers all biomedical research in laboratory settings involving biohazards but does not sufficiently define biohazards or biomedical research. The scope combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may primarily affect animals, plants, agriculture or the environment, or research involving materials that may affect human health, but are not considered biomedical research (e.g. environmental sciences).

The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Recommend that the scope be broadened to a One Health approach developed in collaboration with other funding agencies to ensure adequate oversight of animal, plant and environmental hazards while minimizing administrative burden.

Toxins: The toxin and protein scope of the policy should be calibrated to meaningful risk. The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses "prions and other self-aggregating proteins" in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

The proposed definition of genetic modification includes passaging, reassortment, and chemical or

radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Genetically modified cells: Human and non-human primate-derived cells are commonly recognized to present potential risk to human health; however, the risk to human health associated with many animal (e.g., murine) or insect cell lines is often ambiguous, negligible and case-specific. We recommend clarification and specific examples of genetically modified and primary cells covered by the policy per Section IV-2. We similarly recommend clarification and examples of well-characterized cell lines as referenced in Section IV-3.

Genetic modification: Considering the potential for unintentional or collateral mutagenesis induced by experiments involving ionizing irradiation and/or chemicals, we suggest adding the term intentional (or a term with similar meaning) to the definition of genetic modification per Section II.
Section IV-2 requires Institutional Biosafety Committee (IBC) review and approval before initiation of a rather broad scope of research involving genetically modified cells, viruses or organisms, other than plants. Conversely, Section IV-3 allows for delegated review of a much more specifically defined subset of research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes. This distinction suggests that NIH intends for IBC review and approval of research involving replication-competent, integrating viral vectors expressing high-risk transgenes; however, the language in Section IV-2 may be interpreted to encompass any genetic modifications not specified in Section IV-3. For example, if vertebrate animals are considered organisms, this suggests that all genetically modified vertebrates (e.g., transgenics) may require IBC review and approval. In addition, Section IV-2 may be interpreted to apply to any and all cells not involving plants (e.g., animal and insect cells). We recommend that Section IV-2 be modified to more explicitly describe the nature of research involving genetic modifications subject to IBC review and approval before initiation (e.g., research involving genetically modified cells, viruses or organisms deemed potentially harmful to human health or subject to Section IV-3).

Transgenic animals: Recommend providing a definition of transgenic as referenced in Sections IV-3 and V-A.

Clarify oversight related to genetically modified and/or transgenic animals. Section II limits the Policy to research involving “known or potential risk to human health.” Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both. The final policy should apply the Section II threshold to transgenic animal research and include an exemption from the policy for the following with transgenic animals: Breeding, maintenance,

cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).

Define the coverage of recombinant and synthetic nucleic acid molecules. The draft policy defines scop primarily through biological agents and genetically modified cells, viruses and organisms and does not explicitly state how standalone rDNA molecules are treated. NIH should clarify if standalone nucleic acid molecules are intentionally outside the scope of this policy and if not, identify the circumstances under which they become covered.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Delegated review is a welcome modernization, but requiring every approval to be reported "in full" at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee's role after delegated approval should also be defined.

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish exemptions or administrative registration/reviews.

3. Continued utility of Risk Groups: Retain Risk Groups as a starting point, but do not rely solely on their use for oversight. Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations. Oversight categories and containment decisions
should rest on experiment-specific risk assessment and the BSL/ABSL framework.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No additional comments now

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes. NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents and clarify what information is necessary to achieve meaningful public transparency. NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes
6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Per Section III-B, IBC Functions:
"Minutes should be posted immediately after approval and once all appropriate and allowable redactions have been made."
In reflecting on (1) the time required to edit minutes, (2) the mechanics of posting on a public-facing webpage, and (3) holiday and staffing considerations, reasonable time should be afforded to IBCs to meet the posting requirement. We suggest an allowance to post within five to ten business days after a convened meeting.
Please clarify whether the IBC is confined to using the NIH-provided table in the IBC meeting minutes template, or whether the IBC may use a different format while publishing all required elements listed in the template.

6. Other feedback relevant to this resource: Additional clarification and inclusion of guidance, examples, or suggestions for institutional positions (e.g., Vice President for Research, Associate VP for Research Compliance, IBC Coordinator/Administrator) deemed suitable by NIH to fulfill the role of Authorized Organizational Representative (AOR).
Additional clarification regarding the role of the IBC in Section III-B would be helpful, particularly around expectations for "evaluating the expertise of personnel involved in research." What, if any, actions are expected of the IBC in response to the information supplied by the applicant?
Per Section III-B, Biological Safety Officer (BSO): The BSO's duties include, but are not limited to:

“Conducting periodic inspections to ensure that laboratory biocontainment facilities and equipment are functioning properly, biosafety standards are rigorously followed, and IBC approval conditions for the conduct of research are being followed.”
The term ensure appears to suggest that BSOs have enforcement authority, which is atypical of the role as conventionally understood. We suggest replacing ensure with language (e.g., assess, verify) that more accurately reflects the conventional consultative and advisory role of the BSO. We suggest that the BSO’s observations from such assessments be reported in accordance with institutional policies and procedures.
Draft policy retains the requirement for an institution to have a BSO if there is research at BSL-3 or higher. However, since the draft policy does expand the responsibilities of the BSO and the IBC, recommend that a BSO be identified for any institution with research at BSL-2 or higher.

Description: Comments on Draft NIH Biosafety Policy

277. Charles River Laboratories- Montreal/Senneville

I am responding: On behalf of an organization

Name: Alyson Guy

Name of Organization: Charles River Laboratories- Montreal/Senneville

Type of Organization: Other

Type of Organization - Other: Contract Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Safety Toxicology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: One concern is the apparent scope of the policy. It is not clear whether the requirements apply only to NIH-supported activities or to all biohazard work conducted by an institution participating in NIH-funded research. If the latter, compliance could become very difficult, if not impossible, for some institutions. The policy should clearly define the intended scope and explicitly state whether requirements apply solely to NIH-funded activities or to all biohazard work performed by the institution. Consideration should also be given to the differing operational environments of universities versus private research organizations, which may operate under different confidentiality, proprietary information, and oversight frameworks.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Based on our interpretation of the draft policy, the majority of our work would likely fall under Section IV-3, requiring subgroup review and approval. We recommend NIH evaluate whether the proposed oversight structure is appropriately calibrated to risk and whether the volume of activities requiring higher levels of review may create unnecessary administrative burden without a commensurate biosafety benefit. Clear examples and guidance regarding activity categorization would be beneficial.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary adoption of the policy may be challenging for certain institutions, particularly private research organizations that operate under strict confidentiality and proprietary information requirements. NIH should consider providing flexibility for institutions that are not federally funded or otherwise subject to the policy, including alternative methods for demonstrating transparency and accountability without requiring public disclosure of sensitive institutional information.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We have significant concerns regarding the public posting requirements in the draft policy and associated templates. Section

III-A requires that IBC meeting minutes and incident reports be publicly posted for a minimum of five years. Section III-B further requires approved meeting minutes to be posted on a public-facing institutional website using the prescribed template. The draft meeting minutes template indicates that the names of IBC members and principal investigators may not be redacted. These requirements may be incompatible with institutional privacy expectations, confidentiality obligations, and security considerations. NIH should consider allowing greater flexibility regarding public disclosure, including the ability to redact personally identifiable information and sensitive operational details where appropriate.

6. Other feedback relevant to this resource: Additional implementation guidance is needed regarding IBC membership requirements. The requirement to include at least two unaffiliated community members may be difficult for some organizations to fulfill. Many institutions already experience significant challenges recruiting and retaining community members for other oversight committees such as IACUCs. NIH should consider alternative approaches or additional flexibility for institutions that cannot readily identify qualified community representatives.

Additional guidance would also be helpful regarding public posting requirements, confidentiality protections, and the applicability of the policy to private-sector research organizations.

278. Dr. Mark Peifer

I am responding: On behalf of myself

Name: Dr. Mark Peifer

Name of Organization: University of North Carolina at Chapel Hill

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Molecular and Cellular Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Defining transient expression via mRNA delivery as a form of "genetic modification" makes no sense, and would needlessly restrict fundamental research and preclincal applications. Genetic modification changes the genome in a heritable way, and that should be the definition.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

279. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed scope would benefit from greater precision to support consistent application across varied institutional settings. The final policy should define “research” and “biohazard” clearly and distinguish covered research from clinical diagnostics, public-health testing, assay verification and validation, routine analytical testing, product-support testing, and other activities that use biological materials without seeking generalizable knowledge. Terms such as “potential,” “acceptable,” and “significant risk” should be accompanied by objective criteria, a decision tree, and representative examples for academic, contract-research, analytical, and public-health settings.

Institutions also should be able to rely on reasonable, documented classification decisions made in good faith under then-current NIH criteria and examples, unless the decision was based on a material omission or is affected by new information or a material change in the work.

NIH should clarify the organizational boundaries of a covered institution, the meaning of research “sponsored by” an institution, and the treatment of affiliates, subsidiaries, separately incorporated locations, subrecipients, subcontractors, and client-sponsored activities. Potential oversight gaps involving recombinant plant and plant-pathogen research should be addressed through risk-based criteria developed in coordination with USDA or another appropriate federal agency.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered system is appropriate if federal oversight establishes clear minimum requirements while preserving local authority to apply project-specific judgment. Federal review or mandatory standards should focus on activities involving substantial hazards, novel agents, high uncertainty, or national-security implications. Institutions should be able to use documented administrative or delegated review for well-characterized, low-risk activities and reserve full IBC review for work whose hazards, uncertainty, or proposed controls warrant committee deliberation.

The final policy should identify the federal authority responsible for administering an expedited process for emerging, novel, or zoonotic agents when no current risk-group recommendation exists. That process

should include interim containment recommendations, defined submission requirements, points of contact, decision timelines, and time-limited emergency determinations so that appropriately qualified laboratories can perform urgent diagnostic, assay-development, and countermeasure work under defined minimum controls.

NIH should specify which project-review requirements are satisfied by equivalent federal oversight and which institution-level obligations—such as assurance, reporting, training, recordkeeping, and public posting—remain applicable.

3. Continued utility of Risk Groups: Risk Groups remain a useful baseline for understanding the intrinsic hazards of agents and should be preserved in an authoritative, publicly accessible federal resource. They should not, however, be treated as a stand-alone containment determination, particularly when an agent is genetically modified. Institutional risk assessment should consider whether a modification may alter host range, pathogenicity, transmissibility, environmental stability, treatment susceptibility, toxin production, or other relevant characteristics, and should select practices, equipment, and facility controls using the BMBL.

NIH has stated that implementation resources will draw from current Risk Group classifications and other existing guidance. The final policy should expressly preserve those resources until authoritative replacements are published, clarify the relationship between RG and BSL, maintain a searchable record of generally applicable determinations for previously reviewed experiment types, and confirm that existing approvals remain valid unless new information or a material change warrants reassessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary compliance is most likely when NIH offers practical tools and clear incentives rather
than extending mandatory requirements indirectly. Useful resources would include modular model policies, decision tools, training materials, sample risk assessments, and adaptable templates that institutions may adopt without becoming subject to unrelated funding requirements.

A tiered recognition or self-attestation program, confidential technical assistance, and access to the centralized incident-learning system would further encourage participation. NIH also should make clear how voluntary adoption affects an institution's legal and programmatic obligations, including that use of NIH tools or templates does not by itself create additional public-disclosure duties or implied certifications beyond the practices expressly adopted

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We support appropriate reporting and accountability for significant biosafety incidents and compliance failures. The templates should identify minimum data elements while allowing
institutions to use equivalent records and systems. The incident-learning function should encourage timely reporting, root-cause analysis, corrective action, and sector-wide learning, while preserving appropriate enforcement for willful misconduct, material nondisclosure, or repeated noncompliance.

The proposed National Biosafety Data and Safety Analysis Center could advance those objectives by aggregating, de-identifying, and analyzing incident and near-miss data. NIH should use that

centralized mechanism as the principal vehicle for public learning. Institutional reporting should support transparency, accountability, and corrective action, while institution-level public posting should be limited to information that can be disclosed without compromising privacy, security, legal obligations, proprietary information, or client confidentiality.

Although the draft contemplates allowable redactions, NIH should establish objective withholding and redaction standards so transparency obligations are applied consistently and do not inadvertently create safety, security, privacy, or legal risks. Institutions should not be required to publish information that could identify personnel or facilities, compromise physical security, cybersecurity, personnel safety, or appropriate access controls, disclose restricted or classified information, conflict with applicable legal or sponsor restrictions, interfere with an investigation, or expose proprietary research information. Public outputs should focus on aggregate trends, lessons learned, contributing factors, corrective actions, and other information that advances public understanding without increasing operational or security risk.

The meeting-minutes template should document attendance, quorum, recusals, risk determinations, required controls, votes, and action items without requiring sensitive protocol details to be reproduced in public-facing records. It should allow restricted information to be reviewed by an authorized subset or designated official and referenced in non-sensitive minutes. NIH should also clarify how public-posting requirements interact with the Federal Select Agent Program, classified and controlled information requirements, privacy obligations, contractual restrictions, law enforcement activities, and other applicable federal requirements.

6. Other feedback relevant to this resource: Additional implementation resources will be important to the clarity, consistency, and scalability of the future national framework. NIH should provide a scope decision tree; examples distinguishing research from diagnostics, validation, analytical, and product-support activities; risk-tiering and delegated-review criteria; an expedited pathway for emerging agents; and a maintained resource for
RG assignments and generally applicable determinations for previously reviewed experiments.

Guidance is also needed on institutional applicability, organizational boundaries, subawards and subcontracts, client-funded work, amendment thresholds, grandfathering, de novo renewals, review timelines, training documentation, institutional registration, PI and biosafety-official responsibilities, multi-site programs, and the relationship to Select Agent, USDA, biosecurity, classified, and other access-control requirements. The final policy should allow equivalent institutional systems and documentation when they satisfy the substantive requirements.

The draft proposes an effective date six months after publication of the final policy. NIH should consider whether that period is sufficient for institutions with large portfolios, multiple sites, or high volumes of short-duration projects, and whether a longer or phased implementation period with prioritized milestones would better support orderly implementation. Existing approvals should remain valid during transition unless new information or a material change warrants reassessment.

280. University of Washington

I am responding: On behalf of an organization

Name: Zara Llewellyn, PhD

Name of Organization: University of Washington

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical research, life sciences, molecular biology, genetics, immunology, oncology, infectious disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Full response is in the attached PDF.

Key Issues:

* Policy contradicts itself on RG1 organisms—states RG1 excluded but then requires review of genetically modified RG1 organisms

* "Biohazard" definition depends on undefined phrase "known or potential risk to human health" with no threshold

* Scope expands to non-NIH-funded research at NIH-funded institutions without clear boundaries

* Policy addresses RG2 agents, zoonotic agents, and environmental risk without coherent One Health framework or clarity on interagency jurisdiction (USDA, EPA, FDA)

* Expansion includes currently exempt Section III-F research (transgenic rodents, plasmids, genetically modified cells) without demonstrable safety benefit

Requested Actions:

* Exclude RG1 organisms unless genetic modification creates human health hazard

* Define "biohazard" with a credible risk threshold (not merely theoretical)

* Establish clear interagency jurisdiction framework

* Create exemptions or registration-only pathways for well-characterized, minimal-risk activities currently exempt

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Full response is in the attached PDF.

Key Issues:

* Policy lacks clear allocation of responsibilities: PI should own experiment-level risk assessment; IBC should approve agents/classes and set containment floors; NIH should review genuinely novel or high-consequence questions only

* "Material amendments" undefined—phrase "potential impact on biosafety assessment" is too vague to support consistent compliance

* Delegated review lacks operational clarity and flexibility for institutional variation

* No administrative-burden analysis; six-month implementation deadline is unrealistic

* Policy greatly expands IBC workload (wild-type RG2, genetically modified cells, primary cells, toxins, non-NIH-funded work, delegated review reporting, mandatory templates) without demonstrating federal capacity to handle NIH-level reviews

Requested Actions:

* Define clear PI/IBC/NIH roles and decision thresholds

* Define "material amendment" with examples of changes requiring vs. not requiring re-review

* Allow exemptions, notification categories, delegated review, and umbrella protocols for low-risk work

* Provide 24-month phased implementation with administrative-burden analysis

* Conduct federal capacity analysis for NIH review function

3. Continued utility of Risk Groups: Full response is in the attached PDF.

Key Issues:

* Many organisms lack RG classification; policy requires NIH approval for "emerging, novel, or zoonotic agents" without guidance on interim institutional determinations

* Risk assessment for genetically modified organisms needs guidance beyond RG classification

Requested Actions:

* Provide guidance for institutional classification of likely-RG1 organisms lacking published information

* Establish national Risk Group and containment-determination database; allow institutions to rely on NIH precedents

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The policy lacks mechanisms to encourage or support voluntary compliance at institutions not subject to the policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Full response is in the attached PDF.

Primary Issues:

* Prescriptive format conflicts with accessibility standards

* Duplicates content already in IBC applications, creating administrative burden without safety benefit

* Unclear which sections are mandatory vs. optional

* May inadvertently dictate how IBC meetings are conducted

Key Recommendations:

* Establish minimum content requirements only; allow institutional format flexibility

* Specify institutional capacity differences (600+ active protocols vs. small institutions need different approaches)

* Permit formats compliant with state digital accessibility laws

* Eliminate redundant sections; focus on decisions/discussions, not reproduction of application materials

* Clarify: Can institutions combine prior business and minute approvals? Must unapproved minutes be posted? Can minutes approval occur at the next regular meeting without special session?

DRAFT INCIDENT REPORTING TEMPLATE

Primary Issues:

* Public posting of incident reports with PI name and other information should not be required. Condensed summaries with de-identified information are suitable for public sharing.

* Template and policy language conflict on which incidents require public posting vs. federal reporting:

Do all incidents post publicly, or only those reported to NIH?

* Template format prescriptiveness conflicts with state accessibility requirements

Key Recommendations:

* Align incident reporting thresholds and definitions between policy and template

* Clearly specify which incidents require: federal 24-hour reporting / public posting / local management only

* Allow institutions to adapt template format while maintaining content requirements to meet state accessibility standards

* Define "appropriate and allowable redactions" with specificity

6. Other feedback relevant to this resource: Full response is in the attached PDF.

Core requirements are deferred to future supplemental materials, but institutions have only 6 months to bring new and ongoing research into compliance. A complete overhaul should not be finalized until operative guidance, templates, examples, decision rules, and implementation resources are available for public review as an integrated package.

Essential materials NIH should provide:
* Biosafety Assurance template with completion guidance

* Model institutional policies and decision trees

* Risk-assessment forms with worked examples covering modern virology and biotechnology

* IBC meeting-minutes and incident-reporting templates refined per feedback

* Training modules for IBC members, BSOs, PIs, and laboratory staff

* Sample completed minutes and incident reports

* Uniform redaction standards and guidance

* National Risk Group and containment determination database (searchable, with precedent guidance)

* Clear decision rules mapping current NIH Guidelines to new framework with examples

* Guidance on delegated review implementation

Administrative-Burden and Capacity Analysis: NIH has not published analysis of institutional workload

required or federal review capacity available.
Request:

* Conduct administrative-burden analysis before finalization

* Publish realistic estimate of institutional and federal workload

* Demonstrate federal capacity to handle increased NIH approval requests

Implementation Timeline and Phased Approach: 6 months is insufficient.
Request:
* Extend effective date to minimum 24 months after publication of all final materials

* Provide phased implementation with defined milestones:
1) Governance and assurance infrastructure (Months 1–6)

2) Higher-risk work transition (Months 7–12)

3) Mid-risk work transition (Months 13–18)

4) Lower-risk and legacy protocols (Months 19–24)

* Include provisional or deemed assurance mechanisms to prevent research interruption

Targeted Support for Smaller and Less-Resourced Institutions

Request:

* Provide dedicated biosafety supplements or cost-allowability provisions (not unfunded mandate)

* Develop workforce development programs and shared training resources

* Support flexible institutional models (shared IBCs, external services, consortium arrangements)

* Provide tools for mutual-aid arrangements in underserved regions

Binding Guidance and Interpretation Mechanisms

Request:

* Provide mechanism for institutions to obtain binding interpretations during implementation

* Establish clear precedent-setting process for published NIH determinations

* Create process for institutions to request waiver or variance from prescriptive requirements

Uploaded File: University-of-Washington-feedback-on-NIH-Draft-Biosafety-Policy_Oct-2026.pdf

Description: University of Washington Feedback on NIH Draft Biosafety Policy NOT-OD-26-112

ENVIRONMENTAL HEALTH & SAFETY
UNIVERSITY of WASHINGTON

October 16, 2026

NIH Office of Science Policy (OSP)
6705 Rockledge Drive, Suite 630
Bethesda, MD 20892

RE: NOT-OD-26-112

Dear NIH Office of Science Policy:

The University Washington (UW), through its Environmental Health and Safety Department (EH&S) and Institutional Biosafety Committee (IBC), submits these comments in response to the August 19, 2026, notice "NIH Releases Draft Biosafety Policy for Research Involving Biohazards for Public Comment," Notice NOT-OD-26-112.

The UW supports thoughtful biosafety regulation that promotes safe, responsible, and compliant research. The NIH draft Biosafety policy has significant implications for UW given the scale and breadth of our research enterprise and the more than $1.2 billion in federal research funding we receive annually. As a leading U.S. research university, UW has a strong interest in ensuring that the policy advances biosafety objectives while providing a clear and effective framework for institutional oversight of research involving biohazardous agents.

The UW supports the effort by the National Institutes of Health (NIH) to undergo a comprehensive review and evaluation of the NIH Guidelines, given the advances and changes in biomedical research and in the field of biosafety and biosecurity. The draft policy represents a substantial effort to modernize biosafety oversight for evolving research technologies and practices. However, as drafted, it cannot be implemented consistently or proportionately within a six-month timeframe. NIH should use the public comment period to substantially revise the policy, provide complete implementation resources, and reissue for broader stakeholder review before finalization.

The modifications requested in this comment will support NIH's stated goals of safe, proportionate, evidence-based, and consistent biosafety oversight while enabling institutional implementation that does not displace resources from higher-impact biosafety activities.

201 Hall Health Center, Box 354400, Seattle, WA 98195-4400

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HIGH LEVEL FEEDBACK ON THE DRAFT BIOSAFETY POLICY

1. **Scope Expansion Without Clear Boundaries:** The draft policy substantially expands IBC review requirements beyond the current NIH Guidelines but lacks sufficient clarity to enable consistent institutional implementation. Requirements for IBC review are expanded to include transgenic rodents, research with plasmids, cloning in lab strains of *E. coli* and yeast, and well-characterized cell lines of any species, research that is currently exempt (Section III-F) under existing NIH Guidelines. This expansion would redirect institutional biosafety resources and IBC capacity toward review of well-characterized, minimal-risk activities without demonstrable improvement in biosafety oversight or risk reduction.

   Request: Narrow and clarify the scope explicitly and ensure internal consistency. Establish clear criteria for when research must be reviewed versus when institutional processes or exemptions suffice. Exclude RG1 organisms unless genetic modifications demonstrably create a human health hazard.

2. **Administrative Burden Without Demonstrated Safety Benefit:** New requirements for IBC documentation, risk assessment, incident reporting, and public posting significantly increase administrative burden on biosafety professionals and IBC members without corresponding improvements in biosafety oversight or risk reduction. Biosafety time and resources are better invested in high-impact activities such as facility inspections, staff training, and incident investigation than in administrative compliance tasks and template reproduction. The additional transparency requirements are burdensome with little added safety value and potentially divert attention from higher-risk oversight.

   Request: Conduct and publish an administrative-burden analysis before finalization. Authorize proportionate mechanisms such as exemptions, notification-only categories or registrations, staff or biosafety officer review, and clear amendment thresholds.

3. **Unrealistic Implementation Timeline:** Six months is insufficient for institutions to inventory covered research; re-review existing research; revise internal policies and systems; train staff, IBC members, and researchers; and implement new processes.

   Request: Extend the effective date to at least 12 months with phased implementation up to 24 months after publication of final policy and complete

implementation resources. Provide phased milestones (e.g., governance and assurance infrastructure first; then higher-risk work; then lower-risk and legacy protocols).

4. **Critical Gaps in Definitions, Scope, and Guidance:** The policy employs key terms without defining them, contains contradictions between policy sections and templates, and lacks examples or decision criteria necessary for consistent implementation. Examples of undefined or contradictory terms include:

    - Risk Group 1 organism inclusion/exclusion ("genetically modified organisms" applied to RG1)
    - "Well-characterized cell lines" (species, criteria, genetic modifications)
    - Clinical research ambiguity
    - "Periodic" post-approval monitoring
    - Delegated review procedures and expectations

    Request: Provide precise, operationally useful definitions with decision criteria and worked examples.

5. **Lacks Modern Virology and Viral Vector Guidance:** The policy as written does not provide a framework adequate for assessing modern virology. It should include examples and criteria for replication competent and replication defective viruses, single-cycle viruses, viral vectors, pseudotyped particles, virus-like particles, replicons, and infectious clones. The current terms of the policy are not adequate to describe modern virology research.

    Request: Add a technically complete framework for viral vectors, replicons, helper systems, infectious clones, and clinical gene-delivery platforms with worked examples and risk-assessment criteria.

6. **Inflexible Template Requirements:** The proposed IBC minutes and incident reporting templates are prescriptive in format, duplicative of existing documentation, and do not accommodate institutional variation in size and operational model. Additionally, tables with text are unreadable by screen readers; if the template format is required to be a table, this template would not meet accessibility standards, which are required for documents posted on our public institution’s website.

Request: Establish minimum content requirements and allow institutional flexibility in format and structure. Permit institutions to adapt templates to state and federal accessibility obligations and operational workflows. Acknowledge that institutions managing 600+ active protocols require different documentation approaches than smaller institutions.

DETAILED FEEDBACK ON THE DRAFT BIOSAFETY POLICY

Section II.

Scope

- **Policy Definitions:** The UW recommends that broadening the applicability/scope of the policy should be based on scientific expertise and data. Before establishing definitions, NIH should assess the current landscape together with a panel of experts (after receiving comments). Specifically, definitions of biomedical research, biological agent, and novel agent or organisms are broad and inconsistent. In addition, the NIH's authority for biomedical research should not expand outside of the NIH's authority, which is limited to NIH-funded research.
- **Risk Group 1 organisms:** The policy as written is contradictory. It states that Risk Group (RG) 1 organisms are not included but genetically modified RG1 organisms are. Since human health hazards are the intended scope, RG1 organisms should not be included in the policy. An exception would be genetic modifications that cause a RG1 organism to become pathogenic or hazardous to human health. Removing RG1 organisms from the scope would also eliminate most standard cloning in lab strains of E. coli and yeast, which is similar to exempt experiments in the current NIH Guidelines.
- **Implementation timeline:** Six months for implementation is unrealistic for most institutions. Extend the effective date to at least 12 months and up to 24 months. Allow a phased implementation to provide updates to training, processes, application forms, resources, and to test new and adjust new programs.
- **Dual review/clearance when two sets of regulations apply**: "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." State clearly what the other regulations or purviews are and how this clearance would be obtained and if this research is also subject to the NIH Biosafety Policy.

General Definitions

- **Research clarification and scope:**
    - Clarify if "biomedical research" includes teaching laboratories and student organizations, where students conduct projects that may involve biohazards.
- **Research clarification and scope:** Clarify if "biomedical research, in laboratory settings" includes teaching laboratories and student organizations, where students conduct projects that may involve biohazards.
    - Clarify if clinical research in health care settings involving human blood, body fluids only, is out of scope of this policy.

Section III. Roles and Responsibilities

- **IBC and PI Risk Assessment Purview:** Preserve PI ownership of experiment-level risk assessment while defining proportionate IBC review roles. The IBC should not be required to separately document a risk assessment for each individual assay, procedural variant, or routine experiment of a PI's research.

Section III-B. Responsibilities of the Institutional Biosafety Committee (IBC)

IBC Functions

- **For IBC Meeting Minutes requirements:** Unapproved meeting minutes should not be required to be publicly posted. Confirm that meeting minutes are voted on at the next scheduled convened meeting and do not require additional meetings solely to vote on the prior minutes.
- **De novo reviews:** Clarify if a 3-year renewal application that is substantially the same as a new application meets the requirement for de novo review.
- **Post-approval monitoring:** The Policy states: "Periodically reviewing approved research conducted at the institution, to ensure compliance with the conditions established in the IBC approval and with the Policy. This responsibility may be delegated to the BSO or other staff, as appropriate." Provide a definition for "periodic" and the acceptable methods to achieve this. For example, are protocol amendments, renewals, or biosafety lab inspections adequate?
- **Provide definitions and examples related to incidents:**
    - Define "incident" and ensure it matches the description on the Incident Reporting Form.
    - Clarify if a "potential laboratory-acquired infection (LAI)" would include instances when post-exposure prophylaxis is routinely given.

  - Provide examples of BSL-3 equipment failures that require reporting. For example, is reporting a biosafety cabinet in alarm because of HVAC issues a reportable incident?
  - Provide examples of "inventory or security" issues with public health consequences.
  - Define "basic first aid."
  - Define a "compliance violation incident" that requires reporting. Does that mean a violation of this policy specifically (i.e., failure to obtain IBC approval prior to conducting work) or compliance beyond this policy?
  - Define "minor" and "low risk" spills. Does low-risk encompass BSL-1 and BSL-2? Clarify what characteristics of a spill would classify it as "minor" (e.g., volume, composition, location).

- **Public posting of incidents:** We are strongly against public posting of incidents without more redactions to remove identifying details. Required public posting of all biosafety incidents and near misses with the PI name will result in decreased reporting of incidents and will increase the collective biosafety risk to the research community. Including PI names, organism names, and identifying details of research does not contribute to incident metrics, patterns, and lessons learned.
- **Incident Reporting Thresholds:** Specify which categories of incidents require federal reporting within 24 hours, and which may be managed through local institutional procedures. Provide explicit definitions of reportable incidents, biosafety-related incidents, compliance violations, first-aid events, and minor spills to ensure consistent classification. We are strongly against public posting of incidents.
- **Reporting of lower risk, non-NIH reportable incidents:** The UW's stance is that non-NIH reportable incidents, and any incidents, should not be required to be posted on a public website. For non-reportable incidents, establish a proportionate documentation approach such as annual or semi-annual aggregate reporting rather than detailed written reports for each individual minor event, similar to annual OSHA logs. For non-reportable incidents, establish a proportionate documentation approach such as annual or semi-annual aggregate reporting rather than detailed written reports for each individual minor event, like annual OSHA logs. This approach would reduce administrative burden while maintaining records for audit and trend analysis and lessons learned.

- **Post-exposure prophylaxis:** NIH reportable incident includes "any incidents involving exposures at BSL-2/ABSL-2 that require agent-specific treatment beyond basic first aid." Does this include post-exposure prophylaxis treatment given before there is a suspected or confirmed lab acquired infection? For example, an occupational health response plan for Treponema pallidum calls for post-exposure prophylaxis treatment with specific antibiotics if an exposure occurs.

Section III-C. Responsibilities of the Principal Investigator (PI)

- **Training on the Policy:** For "coordinating and/or providing appropriate training on the Policy and biosafety requirements applicable to the research being conducted for all research personnel under their supervision": does the PI need to provide training on the Policy in addition to the institutional training? The institutional training on the Policy should be considered sufficient.
- **NBDSAC mention appears misplaced:** The paragraph about reporting to the NBDSAC is in Section III-C. PI Responsibilities. This should most likely be in the Institutional or IBC responsibilities section.

Section III-D. Responsibilities of the National Institutes of Health (NIH)

- **RG1 organism classification guidance:** Regarding the requirement for NIH approval for "research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL," how could this be applied to organisms that are likely RG1 but for which there is no published information? Provide specific guidance for institutions to classify RG1 microorganisms. Provide a description of RG1 organisms to exclude such organisms from requiring an institution to ask for NIH approval.
- **NIH Precedent and Reusability:** The policy anticipates publication of lower-containment determinations but does not state whether another institution may rely on them. Create a searchable national determinations and risk-classification database. Define when an institution may rely on published NIH containment determinations or containment-lowering decisions without seeking independent approval.

Section IV-1. Research That Requires NIH and IBC Approval Before Initiation

- **Clinical studies across multiple sites:** For clinical studies occurring at multiple sites, the UW recommends having provisions for reciprocity or shared reviews across the institutions where the study will take place.

Section IV-2. Research That Requires IBC Review and Approval Before Initiation

- **RG3 agents that can be used at lower biosafety levels:** Clarify if wildtype RG3 agents that can be used at a lower BSL per the BMBL still require IBC review before initiation or if delegated review is acceptable. Examples include wild type HIV and SIV.
- **Select Toxins:** Clarify if IBC review is required for Select Toxins even when the amount used is below the Federal Select Agent Program (FSAP) permissible limits.
- **Expansion of IBC review for currently exempt research:** The Policy states that "Research involving genetically modified cells, viruses, or organisms, other than plants (e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs)" requires IBC review and approval before initiation. This is an expansion of current requirements and includes research currently falling under Section III-F or exempt experiments that do not require IBC review. "Genetically modified cells" is too broad of a category, as many genetically modified cells currently fall under Section III-F and do not constitute a hazard, are low-risk, and do not warrant IBC review.
- **Clarify if RG 1 organisms are included in scope or not:** "Genetically modified organisms" would include modified RG1 microorganisms. This seems to contradict the policy scope that RG1 organisms are not included. Wild type and genetically modified RG1 organisms should be excluded unless the modifications cause the organism to become a human health hazard.
- **Cells with adventitious agents: "**Research with primary cells that may be contaminated by adventitious agents" requires IBC review and approval before initiation." This should only apply to adventitious agents that are human health hazards. And if the adventitious agents are wildtype, to be consistent with the Policy, only delegated review should be required. Cells with adventitious RG2 biological agents should be included in Section IV-3 for delegated IBC reviews for wildtype RG2 agents.
- **Clinical research scope:** The updated clinical research scope is more risk-based but is still not clear. "Capable of shedding, replicating, or integrating" is imprecise and may be interpreted inconsistently for study products such as genetically modified cells, non-replicating viral vectors, and oncolytic viruses. It is unclear if RG1 agents that can replicate or shed (e.g. wildtype bacteriophage that are not a human health hazard) are included in the scope.
- **Research That Requires IBC Review and Approval Before Initiation:** Lower risk research should be allowed to bypass IBC review. It should instead require specific protections to be implemented rather than be subject to case-by-case review. It

should instead require specific protections to be implemented rather than be subject to case-by-case review.

Section IV-3. Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members

- **Describe and clarify how delegated reviews work.** Allow institutions flexibility to determine how to use and implement delegated review specific to their research portfolio.
- **Wild type RG2 organisms:** Not all wild type RG2 organism research presents equivalent risks. Research with well-characterized RG2 organisms under standard conditions should not consume the same review resources as work involving enhanced resistance, aerosol generation, large scale, animal transmission, or altered host range. Allow delegated reviews for routine work and reserve full committee review for higher risk wild type RG2 research.
- **Modified RG1 organisms:** Do not include RG1 organisms in the policy scope if the intended focus is human health hazards.
- **Transgenic organisms** at BSL-1 include most transgenic rodents, which are currently exempt (Section III-F) and do not require IBC review. This expands required IBC delegated review to include transgenic rodents. This low-risk category of research should continue to be exempt, and including it within the scope of the IBC review creates a significant administrative burden, again without a safety benefit.
- **"Research with plasmids"** is very broad and most is currently exempt (Section III-F). This significantly expands IBC review, even if a delegated review, to include currently exempt research. Research with non-hazardous plasmids should not be included in the Policy scope. Instead, state specific instances when IBC review is warranted.
- **Hazardous nucleic acids** are not addressed by the Policy as written. Hazardous nucleic acids include infectious viral genomes, full-length infectious clones, and nucleic acids with delivery systems such as lipids or nanoparticles. These should be differentiated from low-risk plasmids and require IBC review and approval.
- **"Research with well-characterized cell lines"** is very broad and vague. The NIH needs to specify which species cells or cell lines, as many species of cell lines do not present a human health risk. Delegated IBC review should focus on species of cells that are potential human health hazards, such as human, non-human primate, bat, or species with zoonotic disease potential. Also, clarify if "well characterized cell lines" that are genetically modified would put them in the scope of both IV-2 and IV-3.

- **"Research with biological toxin proteins not on the Select Agent list."** Clarify if a "toxin protein" is different from a "toxin." Provide more specificity about which toxins require delegated IBC review and based on hazard, quantity, LD50, etc. If all toxins require review, this will significantly expand IBC review and approval.

Section V-E. Risk Mitigation Strategies and Laboratory Containment

- **Description of universal precautions for clinical research:** The policy states "that for clinical research in clinical settings, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection." The Policy should not include respiratory protection as part of "universal precautions." Requiring respiratory protection should be based on a risk assessment.
- **Biohazardous waste:** The Policy does not mention biohazardous waste. Is the BMBL the primary guidance for what items should be considered biohazardous waste and require treatment prior to disposal? The NIH should define what is biohazardous waste and provide guidance for methods of disposal.

Other questions that are not included in the current sections

- **Risk Group appendices:** The draft Policy does not include appendices or lists with RGs for organisms. The NIH should publish appendices of Risk Group 2, 3 and 4 organisms in the final Policy.

DRAFT REQUIRED IBC MEETING MINUTES TEMPLATE

Allow flexibility in IBC minutes format and detail level to accommodate varying operational models. Rather than mandating the use of a template or a specific table format, establish minimum content requirements and permit institutions to adapt templates to their state and federal accessibility obligations and operational workflows. With new federal accessibility standards, templates will need to be formatted for compliance. Acknowledge that institutions managing 600+ active protocols will require different documentation approaches than smaller institutions.

Primary concerns:

- **Clarity needed on template flexibility and format:** Template flexibility is undefined. State which sections are mandatory or optional, if the format can be adapted, and what level of detail is required. Institutions need flexibility to format the document to their needs while still meeting the minimum requirements.
- **Excessive duplication**: Multiple sections require information already documented in IBC applications and review materials, creating administrative work that diverts resources from meaningful biosafety activities, such as lab inspections and training.

- **Accessibility compliance risk**: The current table format may not meet Washington State digital accessibility standards for posting on our public institutional website. Allow flexible options for, so we request flexibility in document layout and formatting to ensure compliance with state digital accessibility standards
- **Meeting process prescriptiveness**: The template may inadvertently dictate how IBC meetings are structured and run, rather than serving as a documentation tool. Institutions should be allowed flexibility to order and organize the sections to mirror how their IBC meetings operate.
- **Section organization**: Some sections are redundant, misplaced, or lack clear purpose relative to biosafety oversight. Again, provide more clarity around minimum requirements, organization, and allow for flexibility.

DETAILED FEEDBACK ON IBC MEETING MINUTES TEMPLATE:

- **Template Flexibility and Format:** It is unclear whether institutions must use the template exactly as provided or whether format adaptations are permissible. Clarify minimum documentation requirements and allow institutions to adapt format and structure to comply with state accessibility laws and operational needs.
- **Other Individuals in Attendance:** The purpose of documenting others in attendance is unclear and creates an administrative burden. We support removing this as a required section. If documentation of external participants is needed, include only speakers invited to discuss specific projects (e.g., PIs answering protocol questions), and document within the project discussion section.
- **Registration Number:** Including the registration number adds detail that does not enhance biosafety documentation. Project type (i.e., new, renewal, amendment) is more operationally useful. Replace registration number with project status indicator (new, renewal, change/amendment).
- **Project Overview:** Current template requires essentially the entire IBC application to be reproduced in the minutes. Our main concerns include:
    - Requires extensive duplication of information from application and review documents
    - Creates significant administrative burden that diverts time from lab inspections, training, and direct biosafety work
    - Details in this section are repeated later in the BSL Assignment section

  Replace with a high-level summary that includes only operationally relevant information that documents the essential biosafety elements reviewed without duplicating the full application:

    - Agents or organisms being used, including description of genetic modifications

  - General description of laboratory activities and procedures
  - Containment level(s) assigned
  - Special factors affecting containment or safety (e.g., oncogenic inserts, unique equipment, antibiotic resistance markers)
  - Any novel procedures or specialized techniques

- **Readout of Projects Approved by Delegated Review:** Placement in the middle of individual project review is confusing. Delegated approvals should be presented as a separate batch item, not interspersed with full committee reviews, or at least have the option to be a separate item. Our concerns include:
  - Current placement disrupts logical flow of meeting minutes
  - Unclear what level of detail should be documented for delegated reviews compared to full committee reviews, as delegated reviews typically require minimal documentation

  Allow institutions to have a dedicated “delegated reviews” section before or after individual project reviews. Allow documentation of delegated approvals in a simplified format (e.g., list with PI, agent, status [new/renewal/change]) as compiled report, rather than in the same detailed format required for full committee reviews.

- **Risk Assessment and Discussion:** The current template requires listing all activities, equipment, and procedural details, which is information already included in the IBC application. This creates duplicate documentation burden without adding value to the meeting minutes. Instead, consolidate into the Project Overview section. Document discussion notes and IBC concerns or recommendations rather than restating application content.
- **Training:** The template appears to require listing lab-specific training for every project reviewed. If required, this adds documentation burden without biosafety benefit to describe in excessive details of training that are not typically discussed during IBC meetings. At our institution, lab-specific training needs are addressed as part of the biosafety lab inspection. We support documenting the institutional biosafety training status of the PI only. Remove the requirement to include lab-specific training details unless there are unique training requirements from the IBC as part of the risk assessment or training deficiencies discovered during the biosafety lab inspection.
- **Occupational Health Representative Review:** At our institution, occupational health requirements are typically communicated to the IBC through the Biosafety Officer, who coordinates with the occupational health team. We support renaming as "Occupational Health Considerations" and make the section to be used “when applicable” when occupational health issues require specific committee discussion. Allow the IBC

reviewer or BSO to note occupational health requirements without requiring separate presentation by a representative.

- **Biosafety Level (BSL) Assignment:** BSL is discussed in the Project Overview section; repeating it as a separate section creates redundancy. If retained as a separate section, the placement is unclear, and BSL assignment is not applicable to clinical trials. If retained, place immediately after Project Overview. Alternatively, consolidate into the Project Overview section and remove duplication. Clarify that this section does not apply to clinical trial research.
- **Review of Incidents:** Clarify which incidents require review at a convened IBC meeting, such as NIH-reportable or all biosafety incidents, and what details should be included in the minutes.
- **Inspections / Ongoing Oversight:** At our institution, biosafety lab inspections are synchronized with the project reviews, so it makes logical sense to include the biosafety lab inspection update with the Project Description. Allow institutions flexibility in how they report biosafety lab inspection findings based on how they operate.
- **IBC Training:** We recommend having this as an optional section to use when applicable, as IBC training may not be provided at every convened meeting.
- **Public Comments:** We recommend having this as an optional section to use when applicable, as IBC meetings are not required to be open to the public.

DRAFT REQUIRED INCIDENT REPORTING TEMPLATE

- **Clarify which incidents require reporting to NIH:** The incident reporting template contains background information and reporting thresholds that differ from the policy language, creating confusion about which incidents trigger NIH reporting obligations. The policy bases reporting requirements on biosafety levels, while the template expands beyond these thresholds without corresponding biosafety level specification. Align reporting requirements and thresholds between the policy and template and specify the role of biosafety level determinations in triggering federal reporting obligations. Recommend that low risk incidents be exempt from report, e.g. incidents involving RG 1 organisms.
- **Clarify which incidents are required to be posted publicly:** Clarify whether all incidents must be posted publicly or only those incidents required to be reported to NIH. The template and policy language appear contradictory on this point. Clearly specify which incidents are subject to mandatory public posting and provide corresponding guidance on redaction standards and timelines.

- **The UW's stance is that public posting of incident reports should not be required.** The details included in the template can potentially compromise identity and privacy and can result in less reporting of incidents for fear of information being made public. The IBC meetings and minutes will already reflect a discussion of incidents.
- **It is unclear if the incident reporting template's layout and format are prescriptive requirements** or whether institutions may adapt the template format to accommodate minimum content requirements while ensuring compliance with applicable state digital accessibility laws. Allow flexibility so that institutions can fulfill reporting obligations while meeting state-mandated accessibility standards for publicly posted materials.

Thank you for the opportunity to provide feedback on these important considerations for oversight of biological research.

Sincerely,

Institutional Biosafety Committee (IBC)
University of Washington

Environmental Health and Safety Department (EH&S)
University of Washington

281. Rachel Johnston

I am responding: On behalf of myself

Name: Rachel Johnston

Name of Organization: Kennesaw State University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Kennesaw State University

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: • The scope statement that this policy covers "cells, viruses, or organisms, other than plants, that have been genetically modified" introduces extremely broad oversight without a proportional increase in biosafety protection. As written, this would include materials such as:
o Reporter cell lines
o Stable knockout cell lines
o Common transgenic mouse strains already used at ABSL-1, which pose no additional risk than using a wild-type mouse strain
o Common drosophila and Arabidopsis strains already used at BL-1/ACL-1, which pose no additional risk than using a wild-type drosophila or Arabidopsis strain
o Replication-incompetent vectors expressing low-risk transgenes
o Commercially available genetically modified research models
As written, nearly every biomedical research institution would have hundreds or thousands of protocols captured by this policy. While the delegated review category may reduce the burden associated with ongoing review, the initial registration burden remains substantial. IBCs may become overwhelmed reviewing large numbers of low-risk projects that do not present materially different biosafety risks from currently exempt work.
Recommendation: Consider excluding well-characterized genetically modified cell lines incapable of producing infectious agents and posing no greater risk than the parental cell line. Additional exclusions or streamlined pathways should be considered for low-risk genetically modified systems.

• The regulated community would benefit from additional clarification regarding:
o Agricultural and veterinary pathogens
o Plant pathogens
o Clinical research activities
o Environmental and field research
o Arthropod research programs
The boundaries of policy applicability to these areas are not always clear.

• Six months is not sufficient time to implement a policy of this magnitude.
o Implementation will require:
o Revision of institutional biosafety programs
o Revision of IBC applications and registration systems
o Development of new review procedures
o Training of IBC members and biosafety personnel
o Training of investigators and laboratory staff
o Registration of currently unregistered activities
o Review and approval of large numbers of new protocols
Many institutions have substantial portfolios of research that have never previously required IBC review.
Recommendation: Provide at least a 24-month implementation period following publication of the final policy.

Definitions and terminology
• The term "biohazard" is used throughout the policy yet is not formally defined. This creates uncertainty because traditional biosafety programs commonly consider the following to be biohazards:
o Human pathogens
o Animal pathogens
o Plant pathogens
o Biologically-derived toxins
o Recombinant materials
o Human-derived tissues and materials
The absence of a formal definition creates ambiguity regarding the actual scope of the policy.

• The definition of biomedical research references research that falls "within the mission of NIH." This definition will be difficult if not impossible to apply consistently, and leads to the following unanswered questions:
o Who determines whether a research topic falls within the NIH mission?
o What criteria should institutions use?
o How should disagreements be resolved?
A more operational definition should be considered.

• The current definition limits biological agents to bacteria, viruses, fungi, or parasites that cause human disease. However, the policy later addresses:
o Emerging agents
o Novel agents
o Zoonotic agents
o Genetically modified agents
o Prions
o Self-aggregating proteins
The policy should reconcile these concepts so that the definition aligns with the materials actually regulated by the policy.

• The acronym GDMO is used extensively but is not formally defined. A formal definition should be included. Additionally, the policy should further address:
o Gene drive insects
o Gene drive microorganisms
o Attenuated systems
o Non-pathogenic laboratory systems
The current requirement that all GDMO research be conducted at a minimum of BSL-2 appears inconsistent with the policy's broader risk-based framework and with longstanding biosafety principles that containment should be determined through risk assessment rather than solely by the presence of a genetic modification. For example:
o Many attenuated systems present lower risks than wild-type RG2 organisms.
o Certain laboratory insect systems require containment strategies fundamentally different from traditional BSL-2 laboratory design.
Recommendation: Allow BSL designation to remain driven by risk assessment rather than requiring BSL-2 for all GDMOs.

• The current definition restricts toxins to proteins or peptides produced by living organisms. Many biologically derived toxins do not fit this definition.
Recommendation: Align the definition with established Select Agent terminology and existing federal frameworks.

• The policy does not formally define field research. However, the policy repeatedly references:
o Environmental release
o Ecological assessment
o Environmental containment
If field research is intended to fall within the scope of the policy, it should be explicitly defined and addressed within the scope section.

• The policy should include additional definitions on the following types of genetic changes, and where they lie within the scope of this policy.
o Genetic engineering
o Modification resulting from passaging cells
o Modification resulting from reassortment
o Modification resulting from chemical exposure
o Modification resulting from radiological exposure
o Reverse genetics
o CRISPR-Cas9
o Gene knockouts
o Using small RNAs for functions like silencing genes
o Other commonly used molecular biology techniques

• The following terms used within this policy should also be formally defined and reconciled throughout the policy:
o Biohazard

o Biocontainment
o Biosafety
o Biosecurity
o Incident/Near miss
o Notes: Requiring reporting of “any incident” at BSL-3 or BSL-4 could generate large numbers of notifications for events that pose little meaningful risk. In addition, no provision for confirming the legitimacy of an incident is included, and the timeline for reporting is not defined. Note that at my institution, incidents are reported through an online internal system, after which they are routed through one person to assign the incident for review to the correct personnel – incidents involving biological materials are sent to myself as the BSO or one of my direct reports for investigation; however, if the individual who routes the incidents for review is out of office, the institution may technically have been notified, but my group will not have known about it to report it to NIH, nor would we have had time to internally verify the scope and occurrence of the incident. Further, I am notified via E-mail of incidents assigned to me – which essentially means that over the weekend and when I am on vacation, I may not become aware of an incident right away.
o Recommendation: Provide objective reporting thresholds and decision criteria to promote consistency among institutions. Allow institutions to internally confirm the scope and occurrence of the incident prior to making the report to NIH. Clarify the timeline for reporting to take into account different the different reporting types that may come in (E-mail, or routed to different personnel before it gets to the BSO/designee). Please also stratify the reporting timelines based on risk – lower risk events and administrative non-compliance should allow a longer time to report. Additional examples of reportable incidents within the implementation guidance would be valuable.
o Release/ Environmental release/Loss of containment
o Laboratory-acquired infection
o Delegated review
o Containment reduction/Lowered containment
o Approval
o Significant risk/Significant risk to human health
o Potential community risk
o Public posting

• At my institution, the PI does not have all the power to meet the responsibilities listed in this policy, such as:
o Selection of facilities (assigned by the department to the PI)
o Ensuring integrity and maintenance of facilities (performed by facilities maintenance)
o Ensuring integrity of physical containment equipment (performed by EHS)
Please revise the responsibilities section to more broadly allow these functions to be performed by other groups, subject to the makeup of the institution.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): • Section IV-1 proposes NIH review and approval for research involving emerging, novel, or zoonotic agents for which classification or containment recommendations are unavailable in the BMBL. This creates significant practical concerns, as the BMBL contains only a limited subset of organisms encountered in research. At several institutions where I have worked, numerous characterized organisms were routinely utilized that do not appear in the BMBL. As written, the proposal may unintentionally require NIH review for a very

large volume of relatively low-risk work, and this indicates that work will have to stop while NIH reviews work already being safely performed at our institutions. Potential consequences include:
o Delays in protocol approval
o Increased administrative burden
o Bottlenecks at NIH
o Slowed research progress
A risk-based framework must allow institutions and IBCs authority to perform containment determinations for lower-risk agents without halting research for NIH to review proposals. It would be helpful for NIH to update this section to state that they will perform an initial assessment of risk group with a stated expedited turnaround time so that institutions can perform the risk assessments and assign the appropriate BSL for the work at hand.

• The policy creates multiple pathways requiring NIH review, including:
o Novel agents
o Emerging agents
o Zoonotic agents without existing classifications
o Requests to lower containment
However, the policy establishes no review timelines. Institutions need predictable review processes to support grant timelines, hiring, procurement, and project planning.
Recommendation: NIH should establish target review timelines and communicate expected turnaround standards.

• The proposal assumes NIH has sufficient capacity to review potentially large numbers of novel organisms, containment reduction requests, petitions, and classification inquiries. Institutions would benefit from greater transparency regarding anticipated staffing models, expected review volume, prioritization criteria, and contingency plans should submitted requests exceed available review capacity.

• NIH determinations regarding containment levels may have significant impacts on cost, facilities requirements, and project feasibility. The policy should include:
o An appeal process
o A mechanism for reconsideration
o A dispute-resolution pathway
Without such provisions, institutions may have no recourse if they believe a containment determination is unsupported by available science.

• The draft requires appointment of a Biological Safety Officer (BSO) when institutions conduct:
o BSL-3 research
o BSL-4 research
o Research involving GDMOs
However, later language provides that another institutional official may perform these responsibilities if a BSO is not designated. These provisions appear inconsistent. In addition, there is no provision for when a BSO is on vacation or sick.
Recommendation: Include a BSO on the IBC in all cases, not just in higher-risk scenarios. Biosafety

officers provide fundamental expertise in performing protocol review, incident investigation and response, containment determinations, and risk assessments of all research with biological materials at their organization (irrespective of biosafety level, risk group, genetically modified or wild-type status, etc.). Removing BSOs from the IBC unless there is a higher risk portfolio of work at the institution will open up significant gaps in protocol review and risk assessment. Please provide language allowing a BSO to designate another individual in his/her place.

• The policy substantially expands IBC responsibilities, including:
o Protocol review
o Incident review
o Public posting requirements
o NIH petitions
o Continuing oversight activities
For institutions with active research portfolios, this expansion could significantly increase committee workload.
Recommendation: NIH should provide greater flexibility for administrative review, delegated review, and biosafety office functions for lower-risk activities. Additional guidance on effective use of delegated review authority would improve implementation.

• Delegated member review: The policy includes a delegated member review, which is helpful. However, requiring that the approval must be reported in full to the IBC at its next scheduling meeting presents a large burden, and will significantly lengthen IBC meetings and administrative burden for inclusion on the IBC minutes. Please include the provision that the approved protocols which underwent a DMR can be included as a published list within the IBC meeting agenda, rather than discussed in individual detail in the meeting, and that the same list will be published within the minutes. This can be a simplified table including the following fields:
o Protocol number
o Protocol title
o PI
o Agents
o Approved biosafety level

3. Continued utility of Risk Groups: • The draft appropriately emphasizes evaluation of synthetic biology research and constructs generated from multiple sequence sources. However, reliance on the highest Risk Group classification of source organisms may unintentionally result in overly conservative classification when small, nonfunctional, or biologically insignificant genetic elements are incorporated into otherwise low-risk systems.
Recommendation: Emphasize the functional contribution of inserted sequences and resulting phenotype rather than assigning disproportionate weight to the Risk Group designation of the source organism.

• I believe that biosafety levels are still helpful for this field, and align with NIH in their stance that BSLs must be designated based on the actual risk and not solely on the risk group of the base organism. While risk groups give a good starting point, using biosafety levels to help break up different facility design, practices, and procedures into different groupings remains useful for the regulated community. Please retain the utility of risk groups, and allow institutions to continue performing risk assessments, taking

into consideration the characteristics of the biohazard, manipulations of the biohazard, and genetic modifications when assigning a biosafety level. I believe it will be most helpful for NIH to allow its policy to align with the BMBL for the definitions of biosafety levels, and to align with other documents helpful for facility design and assignment of controls (such as the Arthropod Containment Guidelines, and Practical Guide to Containment: Plant Biosafety in Research Greenhouses). If NIH does not wish to rely on sources such as these, NIH should publish within this policy definitions of containment levels it wishes the regulated community to adhere to, including provisions for insect, large animal, and plant work.

• There are several types of research which are so low-risk that IBC review does not actually provide a gain in the field of biosafety. This type of work includes:
o Commercial transgenic animals maintained at ABSL-1
o Low-risk plasmids
o Replication-incompetent non-integrating vectors expressing low-risk transgenes
o Well-characterized cell lines
o Genetically modified RG1 organisms
• These materials should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I did not specifically have comments on this.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: • The proposal would require public posting of:
o IBC meeting minutes
o Incident reports
o Continuously updated committee rosters
o Biosafety program information
I support transparency and public trust. However, implementation of these requirements will create challenges related to:
o Security-sensitive information
o Proprietary research
o Confidential commercial information
o Identification of research personnel
o Dual-use concerns
o Targeting of research personnel
o Protection of laboratory infrastructure details
In addition, preparation of documents for posting will likely require substantial administrative effort to ensure appropriate redactions, without additional support mandated for the offices which will hold this responsibility.
Recommendation: NIH should consider requiring publicly available summaries/tables rather than full meeting minutes and incident reports. Standardized public summaries would promote transparency while reducing the risk of disclosing sensitive information and minimizing administrative burden. Redaction rules must be clearly defined to allow for removal of proprietary and security-sensitive

information.

• Public disclosure will also have another negative impact: This will impede institutions' safety culture, as the template incident report names the principal investigator. This will lead to:
o Decreased privacy for affected individual(s) within small research laboratories, as individuals seeking information will be able to look up the research lab, find the members, and narrow down the possible person who was involved in the incident.
o A "hide the incident" attitude, where, as a result of the bullet above, researchers will not report incidents to the IBC so that their lab is not publicly mentioned in an incident log.
o Inadvertent non-compliance with medical information disclosure.
Please revise the incident template to remove the items to be publicly posted which can lead to a researcher being identified and targeted, including:
o Principal investigator name
o Grant number
Detailed records can be submitted to NIH for oversight, but should not be publicly posted.

• Use of the incident templates, when each institution already has its own means of performing incident investigations, will pose a substantial administrative burden while affected institutions are not given additional resources to cover those additional burdens. Please allow institutions to use their own incident reports (redacting and adding information as needed) to cover this requirement, or include a provision under this policy that additional support for the biosafety office/IBC will be provided to meet the additional administrative burden.

• The policy references record retention requirements under federal grant regulations while simultaneously requiring public posting of certain records for designated periods. Because incident reports may involve multiple protocols, multiple grants, and differing retention schedules, institutions will face uncertainty regarding retention obligations.
Recommendation: Provide a single, harmonized retention framework applicable to biosafety records generated under this policy.

6. Other feedback relevant to this resource: • Additional resources requested:
o Implementation guidance should include decision trees and flow charts for determining containment levels.
o Implementation guidance should include a decision tree for determining whether work is within the scope of the policy.
o Implementation guidance should include a decision tree for when a protocol must go to NIH, vs. go to the IBC, vs. DMR, vs. exempt. This may be combined with the decision tree allowing users to determine whether their work is in the scope of the policy.
• NIH should provide on an annual basis:
o Aggregated reports by region, institution, and biosafety level
o Lessons learned from incidents
o Leading indicators of biosafety
• NIH should continually provide its set precedents – for instance, publicly posting a searchable database which shows risk groups of organisms NIH has set the risk group for, deviations, and whether the prior decision applies to future research at other institutions or for other PIs.

• In the comments above, I have highlighted several areas which will cause an enormous increase in administrative burden. This burden will be held by groups which from my experience are often understaffed and already overburdened without this new policy. A formal regulatory impact assessment should be conducted to estimate institutional costs associated with implementation. Please consider the financial impact of this policy change, and consider dedicated funding supplements and personnel hiring. Many biosafety programs already operate with limited staffing resources, and this policy will significantly increase demands on already constrained biosafety resources. This model will lead to burnout, lack of compliance, and eventual risks to funding.

282. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Draft-Biohazard-Policy-Comments.docx

Response to NIH Request for Comment on Draft NIH Biosafety Policy for Research Involving Biohazards (Notice: NOT-OD-26-112)

1. **Policy Scope:** The policy promotes a risk-based approach rather than a list-based approach, but the definition of what constitutes research with biohazards is excessively broad. Provided examples of biohazards encompass biological entities that are generally not considered to be biohazardous (for example, replicative human cells administered to research participants and self-aggregating proteins such as microtubules).

   Recommendation: Additional scope about what biological material is, or is not, subject to the policy, with examples should be provided.

2. **Required review of historically exempt research:** The stated goal of removing red tape for low-risk research conflicts with expanded review of historically exempt research. The policy does not demonstrate a reduction in administrative burden for low-risk research involving well-characterized laboratory strains (genetically modified RG1 biological agents) and established transgenic animals at ABSL-1. This is currently exempt from the NIH guidelines and represents a huge portfolio of institutional research. Delegated review is presented as streamlining, yet it creates mandatory full reporting, IBC minutes documentation and approval, and public posting.

   Recommendation: Research that is exempt from IBC review under the NIH guidelines should remain exempt in the new policy.

3. **Required review of low-risk research:** The policy requires clarification as to whether replicating cellular therapies in humans are exempt from IBC review. As written, the policy requires IBC review of clinical research involving administration to human research participants of products that are capable of shedding, replicating, or integrating. Replicating cellular therapies include CAR-T cells, a therapy platform that is widely approved by the FDA. CAR-T cells are created by transduction with lentiviral vectors, typically by the sponsor of the clinical trial. Once the transgene is integrated these cells pose little infectious risk.

   Recommendation: Cellular therapies such as CAR-T cells that are created by the clinical trial sponsor outside of the institution performing the trial should be exempt from IBC review under the new policy.

4. **Duplicative reviews; gain of function:** The policy duplicates oversight that will be required by the U.S. Government Policy for Stopping High-Risk Life Sciences Research. The policy requires review of gain of function research that is both recombinant and non-recombinant by an IBC. The U.S. Government Policy for Stopping High-Risk Life Sciences Research also requires reviews of research that meets the definition of dangerous, or potentially dangerous, gain of function research by an IRE.

   Recommendation: The two policies should cross reference one another and provide an integrated framework for compliance.

5. **Duplicative reviews; adventitious agents:** The policy duplicates oversight currently required by the OSHA bloodborne pathogen standard. The policy requires IBC review of research with primary

cells that may be contaminated by adventitious agents. Adventitious agents found in human body fluids and tissues are already regulated by the OSHA bloodborne pathogen standard and its interpretations.

Recommendation: Adventitious agents found in human body fluids and tissues should be exempted from oversight under the policy.

6. **Retroactive reviews:** The policy requires clarification regarding retroactive review of already approved IBC registrations.

   Recommendation: Currently approved protocols should be grandfathered, until renewal, a period not to exceed three years. This is consistent with the three-year IBC approvals outlined in the policy.

7. **Security of Select Agent research:** The policy requires clarification about whether federal select agent program (FSAP) research information should be made available to the public. Much select agent research is conducted in BSL-3 labs. The policy requires publicly-posted information regarding whether the institution conducts research in a BSL-3/ABSL-3 facility. Public disclosure of such research information could present both institutional and national security risks.

   Recommendation: The policy should require IBC review of select agent research but exempt it from public disclosure through redaction of IBC minutes.

8. **Medical privacy concerns:** Public disclosure of incident information could result in compromised medical privacy, and reduced willingness to report incidents. The policy requires posting all incident reports that are both reportable and not reportable to NIH on a public-facing webpage, using the required incident reporting template. This template includes (1) the name of the Principal Investigator, (2) the research materials involved in the incident including full agent name, and description of strain or construct, (3) injury or illness associated with the incident and (4) medical treatment provided. While the policy claims to protect the identify of individuals involved in incidents by not requiring them to be named, it is a straightforward exercise for the public to connect the dots and link the PI name to the people in the lab, especially since labs typically comprise a few individuals and Principal Investigator lab websites frequently name the personnel and their research focus, including the materials they work with. This type of query can be accomplished on a grand scale using AI tools. Given the potential loss of medical privacy, researchers will be less likely to report accidents, which increases the risk of untreated injuries and exposures to hazardous materials.

   Recommendation: The policy should preserve reporting of applicable incidents to NIH but these should not also be required to be publicly posted by the institutions. NIH should make incident reports available to the public but should redact information identifying reporting institutions and PI names to protect medical privacy.

9. **Compromised researcher and animal safety:** The policy requires any incident involving research subject to the policy with an animal that is housed at BSL-1/ABSL-1 containment and above (e.g., bite, scratch, escape or improper disposition) to be posted on a public-facing webpage, using the

required incident reporting template, regardless of whether biohazards were involved. The template includes (1) the name of the Principal Investigator, (2) information on animal species, and (3) the animal procedures being performed at the time of the incident. While institutions such as mine adhere to the highest level of animal welfare requirements, public reports of incidents in animal facilities compromise researcher and animal safety because they can be exploited by animal rights activists. It is a straightforward exercise for animal rights activists to connect the dots as above and identify individuals who are allegedly committing animal abuse. This type of querying can be accomplished on a grand scale using AI tools.

Recommendation: The policy should not require public posting of incidents involving animals. Incident reports involving biohazards should be reported to NIH. Incidents that do not involve biohazards should not require reporting to NIH. NIH should make incident reports available to the public but should redact information identifying reporting institutions and PI names to protect researcher and animal safety.

10. **Resource concerns:** The proposed policy is an unfunded and unsupported mandate. The policy substantially expands institutional responsibilities for IBC oversight, documentation, training, incident review, public reporting, record retention, and oversight of research that may not itself receive NIH funding. We have assessed the administrative and resource impact of the policy and conclude this imposes a significant additional burden on IBC members and will require hiring of additional administrative staff.

    Recommendation: NIH fully fund any such associated indirect costs. NIH should further help institutions to comply by providing comprehensive implementation materials, model procedures, templates, training, and technical assistance.

283. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Virology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support replacing the NIH Guidelines with risk-based biosafety oversight, and I write in support of that objective. My comments identify where the draft Policy does not yet achieve it.

1.1 The draft expands oversight of research NIH has already determined to be low risk, without explaining what changed.

NIH has described this effort as expanding oversight at the high-risk end while reducing burden for low-risk research. The second half has not been achieved. The draft brings within its scope several categories of research that are currently exempt under the NIH Guidelines because the NIH Director affirmatively determined that they do not present a significant risk to health or the environment.

- Propagation of recombinant plasmids in Escherichia coli K-12 host-vector systems, exempt under Appendix C-II where the host carries no conjugation-proficient plasmid or generalized transducing phage and the insert derives from neither an RG3/RG4 or restricted agent nor a potent toxin. Under Section IV-3 the same work becomes "research with genetically modified RG1 biological agents" and requires approval before initiation.
- Transfection of such a construct into a cultured mammalian cell line, exempt since 59 FR 34472 (July 5, 1994) for recombinant molecules containing less than one-half of a eukaryotic viral genome propagated and maintained in tissue culture. Under the draft this is a genetically modified cell, which appears in Section IV-2 as full-committee work and, as a well-characterized cell line or a plasmid expressing a low-risk transgene, also in Section IV-3 as delegable. The Policy states no precedence rule, so institutions cannot determine which tier applies.
- Breeding, transfer and use of BL1 transgenic rodents, exempt under Appendices C-VII and C-VIII. In adopting the breeding exemption at 76 FR 3150 (January 19, 2011), NIH concluded that these experiments "do not pose an appreciable risk to human health or to the environment" and that "the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk."

Generation of such lines is addressed under Section III-E-3, requiring registration at initiation but not prior approval. Section IV-3 would require prior approval for all of it.
- Certain research with RG1 agents not involving sequences from RG3, RG4 or restricted organisms, exempt under Appendices C-II through C-V.

The first two categories deserve particular attention because they are not marginal cases. Construction of expression plasmids and their introduction into cultured cells are the most frequently performed experimental activities in molecular biology and virology laboratories; a single project may generate dozens of constructs in a year. The draft does not state what must be registered — the backbone alone, the backbone with each insert, or each insert with each point mutation — and the answer determines whether this is an annual formality or a continuous bottleneck. Approvals also expire at three years and require de novo submission, so the burden recurs.

The draft offers no revised risk assessment for any of these categories. The cumulative-burden concern NIH identified in 2011 applies with greater force today, and with substantially greater force to routine cloning and transfection than to the rodent breeding it was written about. I ask that NIH either preserve these exemptions expressly or state what evidence supports a changed determination.

1.2 The Policy does not define the terms on which compliance depends.

The Policy is titled for research involving biohazards and does not define "biohazard." It also uses, without definition: organism, transgenic, vector, GDMO, gene drive modified biological agent, adventitious agent, incident, release, shedding, peptide, and potential risk to human health. Several were also undefined in the NIH Guidelines, which makes this the right occasion to correct the problem rather than carry it forward.

"Organism" is the most consequential. It is used inconsistently and is not readily definable, and as written it leaves the relationship between Section IV-2 (genetically modified organisms) and Section IV-3 (transgenic organisms at BSL-1/ABSL-1) unresolvable, because the Policy never says how the two differ. I recommend replacing it throughout with the specific categories intended — bacteria, fungi, archaea, protists, viruses, animals — and stating expressly if there is a further category of concern, such as a biological agent produced through synthetic biology that does not fall within conventional taxonomy.

"Potential risk to human health" carries the entire scope boundary and is undefined. As written it could reach chemical, radiological or physical hazards already regulated by other federal agencies, which I do not believe NIH intends. NIH should define it as the potential to cause human disease or adverse health effects arising from the biological materials within the Policy's scope, state expressly that the Policy does not address non-biological hazards, and identify who applies the threshold and against what standard.

"Toxin" should be limited to substances of living biological origin and should exclude proteins and peptides whose primary adverse effect is an allergic or hypersensitivity response. As drafted, read together with Section IV-3's category for non-Select-Agent biological toxin proteins, the Policy reaches common laboratory reagents of biological origin.

1.3 The definition of genetic modification captures unintentional change and routine virology.

The definition includes stable alterations introduced by passaging, reassortment, or chemical or radiological means, and does not distinguish deliberate engineering from change that occurs incidentally. Serial passage of any virus in cell culture produces unintended genomic alterations; so do chemical mutagenesis, irradiation, and selection under drug pressure. Investigators performing entirely conventional work would be out of compliance immediately and without knowing it.

The definition also reaches nucleic acid molecules that "can be transcribed or translated," which includes transfection of a synthetic mRNA into a cell line. This produces an unexplained inversion: the draft removes deliberate administration of recombinant nucleic acids to human participants from the scope that Section III-C-1 of the Guidelines currently covers, while bringing transfection of the same material into cultured cells within scope. NIH should state the risk assessment supporting the conclusion that the in vitro use warrants review and the in vivo use does not.

I recommend the definition be rewritten to cover intentional, stable modification of the genome, with oversight keyed to the resulting phenotype, and that NIH address expressly how it applies to reverse genetics and viral rescue systems, including recovery of wild-type virus from cloned cDNA.

1.4 There is no review pathway for agents that lack a BMBL entry but are not emerging, novel or zoonotic.

Section IV-1 provides federal review for emerging, novel or zoonotic agents lacking an RG classification or minimum containment recommendation in the BMBL. The Policy provides nothing for the much larger set of agents that are none of those things and still have no entry. Human metapneumovirus, non-polio enteroviruses, human parainfluenza virus 5 and Sendai virus are long-established laboratory agents handled routinely at BSL-2, with no risk group in the NIH Guidelines and no BMBL agent summary statement.

Read literally, they fall into Section IV-1 and require NIH approval — an outcome that cannot be intended, given that wild-type RG3 and RG4 agents require only IBC review under Section IV-2. The same problem applies to human and animal microbiota: if research with common commensal genera requires federal review, it is not clear that an investigator can collect a human or animal specimen without entering noncompliance.

NIH should state expressly that local IBCs may perform the risk assessment and assign containment for agents in this category, reserving federal review for circumstances involving substantial uncertainty or potentially significant public or environmental consequence.

1.5 The Policy does not say who assigns risk groups.

Risk group assignment determines both the review tier and, for RG1, whether research is within scope at all — the Policy places wild-type RG1 agents outside its scope while also stating that absence from the RG2–RG4 listing does not imply classification as RG1. With Appendix B of the Guidelines retired, there is

no authoritative source for these assignments and no stated authority to make them.

NIH should either publish and maintain a version-controlled list of RG1 through RG4 agents supplementing the BMBL, using Appendix B as its backbone and including RG1 agents expressly, or state in the Policy that the local IBC holds that authority. Participation by USDA, CDC and other agencies in a single list, including plant and agricultural considerations, would be valuable.

1.6 Section IV-2 operates as a catch-all with no stated boundary.

Section IV-2 requires IBC approval for initial submissions "not otherwise specified in other sections." A catch-all of that kind requires a corresponding section stating what falls outside the Policy. Institutions cannot operate from isolated bracketed notes, such as the one indicating that experiments with RG1 wild-type biological agents are not subject to the Policy. Without an express out-of-scope section, practice will vary widely between unintentional noncompliance and defensive over-review of work the Policy never meant to reach.

1.7 The relationship to other federal oversight must be stated precisely.

Section II provides that research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained." Section I-A-1 of the current Guidelines is narrower and clearer: another agency's approval may substitute for NIH review or approval. It does not displace institutional IBC oversight. The draft's broader language can be read to eliminate both, and it conflicts with the Policy's own clinical provisions, which require IBC approval in addition to all other regulatory approvals.

Concretely: an investigator registered with the Federal Select Agent Program to work with a wild-type RG4 agent needs to know whether IBC approval under Section IV-2 is still required. An investigator registered with FSAP to construct recombinant viruses in that backbone needs to know whether NIH and IBC approval are required in addition. And an institution needs to know whether an incident in high containment involving a registered Select Agent is reported to NIH and posted publicly, notwithstanding FSAP's own restrictions on security-sensitive information. NIH should state which Policy requirements survive another agency's jurisdiction, and whether approvals are sequential or concurrent.

(Implementation timing is addressed under Question 6.)

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 2.1 The tiered structure is the right approach, and delegated review should be made to work as intended.

The three-tier structure is a genuine improvement over the current framework, and the provision permitting delegated approval of lower-risk research — comparable to the designated member review long used by IACUCs — should meaningfully reduce the time the full committee spends on work that does not require its collective judgment. I also have no objection to bringing wild-type RG2, RG3 and RG4 biological agents within the Policy's scope. Institutions conducting that work already require IBC approval for it, and stating the requirement federally creates no new burden.

Two features of the delegated pathway undercut its purpose. First, requiring every delegated approval to be reported in full at the next convened meeting and included in publicly posted minutes recreates much of the workload the pathway exists to avoid. Institutions should be permitted to provide the committee with a concise approval log or aggregate report, with complete records retained and available for audit, and the Policy should define what role the full committee retains after a delegated approval has been granted.

Second, the Policy should make delegation under Section IV-3 optional rather than mandatory. Institutions differ in committee structure, meeting frequency and administrative capacity, and some will find full-committee review of a given category simpler than administering a delegated process for it. The Policy should also state expressly that delegated review is available for minor amendments — including amendments to research originally reviewed under Section IV-2 — and should distinguish administrative changes from changes requiring reassessment of risk.

Where delegated review is used, the Policy should specify a procedure: notice to all members of a pending review with access to the submission materials; a reasonable period, defined in written institutional procedures, within which any member may request full committee review; assignment of qualified, unconflicted member reviewers; agreement among multiple reviewers, with unresolved differences referred to the full committee; and communication of the approval to the committee for inclusion in its records.

2.2 The Policy provides no rule for resolving overlapping categories.

Sections IV-2 and IV-3 overlap substantially. Genetically modified cells, viruses and organisms appear in Section IV-2 as full-committee work, while several subsets of the same research — well-characterized cell lines, genetically modified RG1 agents, plasmids and non-integrating vectors expressing low-risk transgenes — appear in Section IV-3 as delegable. Nothing in the Policy states which controls. The same construct transfected into the same cell line can be classified in either tier depending on which sentence the reviewer reads first.

The final Policy should state expressly that the most specific applicable category controls, and should include a review-pathway decision table with worked examples spanning full committee review, delegated review, registration, exemption and NIH review. The table should resolve routine cases that will otherwise be decided inconsistently across institutions: transfection of an established cell line, use of a previously edited cell line, a change in personnel, and a change in laboratory room. A room change should not be treated as administrative without first assessing its containment implications. The Policy should also state how de novo renewals are categorized.

2.3 Several categories are placed in tiers disproportionate to their risk.

The categories identified in Section 1.1 above are not merely formerly exempt; they are placed at review levels that do not correspond to any articulated biosafety concern. The Policy does not describe how oversight of this research increases biosafety or biosecurity, and in several cases the administrative burden is substantial while the risk is negligible.

Genetically modified cells, viruses and organisms (Section IV-2). This category is misplaced and internally inconsistent. Genetic modification of cells presents very low biosafety risk absent introduction of nucleic acids from RG3 or RG4 agents or sequences encoding toxins, and such work should be at most within Section IV-3, if not exempt. The category also contains terms that are undefined or poorly defined and that conflict with other categories: as written "organism" appears to include animals notwithstanding the separate transgenic category in Section IV-3; "vector" does not distinguish viral vectors from arthropod disease vectors; and "gene drive modified biological agent" cannot be reconciled with the Policy's own definition of biological agent, while its relationship to the undefined acronym GDMO is unstated.

I recommend this category be removed or extensively rewritten as follows:

- The definition of genetic modification should be limited to intentional stable alterations of the genome, as described in Section 1.3 above. Definitions for organism, vector, GDMO and gene drive modified biological agent must be added to the Policy or the terms removed.
- Research with genetically modified RG3 and RG4 biological agents should require IBC approval.
- Research with genetically modified RG2 biological agents should be eligible for delegated approval.
- Research with gene drive modified organisms should require IBC approval.
- Review of research with genetically modified cells should depend on the modification, with pathways ranging from IBC approval through delegated approval to complete exemption from the Policy.

Research with genetically modified RG1 biological agents (Section IV-3). Certain research with RG1 agents not involving DNA from RG3, RG4 or restricted organisms is exempt under Appendices C-II through C-V, having been determined by the NIH Director not to present a significant risk to health or the environment. This category contradicts that determination without explanation. I recommend it be removed.

Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes (Section IV-3). This research is of low biosafety and biosecurity risk and the Policy does not describe how regulating it advances either. Investigators generate plasmids continuously, and requiring prior approval for them will produce a severe bottleneck and extensive unintentional noncompliance. The Policy also fails to state the extent of what must be registered — the backbone alone, the backbone with each gene to be inserted, or each gene with each mutation of that gene. I recommend this category be removed.

Research with well-characterized cell lines (Section IV-3). The Policy does not identify the biosafety concern this category addresses, nor what must be registered: that an investigator works with cell lines at all, each individual line, or whether an entire catalog may be approved at once. Registration of this work will produce extensive unintentional noncompliance and crippling administrative burden for investigators and committees alike, with no corresponding benefit. I recommend this category be removed.

Research conducted with transgenic organisms at BSL-1/ABSL-1 (Section IV-3). For the reasons given in

Section 1.1, work with transgenic rodents that may be housed at ABSL-1 should not require IBC approval. I recognize that research with some transgenic animals may not yet have accumulated a comparable safety record and should continue to require approval before initiation. NIH should also consider whether transgenic fruit flies and zebrafish warrant exemption on the strength of their own track record. I recommend this category be rewritten as: Research conducted with transgenic animals, other than transgenic rodents, fruit flies and zebrafish, that may be housed at minimum BSL-1/ABSL-1/ACL-1. Consistent with Section 1.2, "organism" should be replaced with "animal" in this category.

Research with biological toxin proteins not on the Select Agent list (Section IV-3). Under the Policy's definition of toxin, this category reaches food and animal allergens and other common reagents of biological origin, which cannot be the intent. There is also a conflict between the category's wording and the definition itself that makes the scope difficult to determine. Work with toxins is in many institutions already overseen by a chemical safety committee, and additional committee review will not increase safety. I recommend this category be removed. If it is retained, it should be rewritten as: Research with biological toxin proteins with an LD_{50} in vertebrates of less than 100 micrograms per kilogram of body weight — and the Policy should include a list of toxins classified under it, using the LD_{50} classification currently available from NIH OSP under Appendix F-1 of the Guidelines as its backbone.

Institutions should additionally be permitted to clear work in any of these categories through a documented internal screening process where that process determines the work presents minimal biosafety risk, and should retain authority to elevate work to a higher tier when local circumstances warrant.

2.4 Primary cells "that may be contaminated by adventitious agents" sits at the wrong tier and rests on an undefined term.

Section IV-2 requires full IBC approval for research with primary cells that may be contaminated by adventitious agents. The Policy does not define "adventitious agent," so institutions cannot determine what is covered. Read literally, "may be contaminated" reaches nearly all primary cell work, including cells from low-risk sources, which conflicts directly with Section IV-3's treatment of well-characterized cell lines as delegable.

The tier assignment is also inverted. Research with material that may contain a contaminant requires full committee review, while research with a known RG2 agent requires only delegated review. For clinical specimens suspected to contain higher-consequence pathogens, the BMBL recommends BSL-2 practices, containment equipment and facilities for routine handling of specimens of human or animal origin. The Policy should harmonize the level of review accordingly.

I recommend this category be removed. If it is retained: "adventitious agent" must be defined — for example, as an unintended biological agent present in cells, tissues, animals or reagents that was not deliberately introduced and is not part of the planned research; "may be contaminated" should be replaced with risk-based criteria tied to the source and screening status of the material, such as unscreened primary human or non-human primate cells; the work should not require approval where the institution complies with the OSHA Bloodborne Pathogens Standard or its equivalent; and in no case

should it require more than delegated review under Section IV-3. If the intent is instead to reach primary cells potentially contaminated by any unknown biohazard, such as field samples, that should be stated and defined.

2.5 Federal review as drafted leaves no path to study a newly identified agent.

Section IV-1 requires NIH and IBC approval for research involving emerging, novel or zoonotic agents for which an RG classification or minimum containment recommendation is not available in the BMBL. For investigators whose research involves identifying previously unrecognized agents, this creates a closed loop. Once an agent is identified and found to have no assigned risk group and no BMBL recommendation, the research requires NIH approval — but without the ability to work with the agent, the investigator cannot generate the data on which NIH would base its risk assessment. The Policy offers no route out of this.

The practical consequence is that this work will not be done in the United States. Investigators will not undertake projects that cannot be initiated, and agent discovery and characterization will shift to institutions in other countries, leaving US researchers dependent on others for the foundational characterization of agents that may later matter a great deal.

The trigger is also drawn far more broadly than the category of genuinely high-consequence uncertainty it appears aimed at. As written it captures many uncommon agents currently handled routinely at BSL-1 and BSL-2, including organisms recovered during environmental screens, and — as described in Section 1.4 — well-established agents that are simply absent from the BMBL.

I recommend the Policy describe a clear approval pathway permitting investigators to generate the data required for a risk assessment, with that review performed by the local IBC. More generally, NIH should consolidate the overlapping petition provisions, define narrowly when an emerging, novel, zoonotic or unlisted agent requires federal review, include an explicit decision rule for the case where reference information is absent, permit qualified IBCs to make interim or final containment determinations for well-characterized agents, and reserve federal preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequence.

2.6 "Emerging agent" is not a stable category and the Policy does not say who applies it.

The Policy does not state who determines that an agent is emerging. If that determination rests with the local IBC, the Policy should say so. If it does not, NIH should issue rapid dissemination notices identifying emerging agents so that institutions can avoid noncompliance with a classification they had no way to anticipate.

The Policy also does not describe how an agent ceases to be emerging. Does the designation persist until NIH first reviews the agent under Section IV-1, until a risk group is assigned, or until the agent appears in the next edition of the BMBL? Nor is it clear whether the definition reaches a well-characterized agent that exhibits a change in pathogenicity or transmission: had this Policy been in effect, it is not evident whether the recent outbreaks of Zika virus, mpox virus or Andes virus would have qualified, or whether

the designation would attach to the agent or only to the specific strain. Applied today, it is not clear which agents would qualify — highly pathogenic avian influenza H5N1, or SARS-CoV-2.

These are not hypothetical distinctions. They determine whether an institution must obtain federal approval before beginning work, and an institution that guesses wrong is noncompliant.

2.7 Recombinant agents constructed within a family should be reviewable by the IBC.

The Policy's definition of novel agent captures recombinant constructs assembled from parental agents that already have assigned risk groups or recommended biosafety levels. Investigators generate such constructs routinely to study the basic biology of these agents — exchanging a gene between two members of the same viral family, for instance, where both parents are well characterized and the containment appropriate to each is already established.

Research of this kind does not fit the Policy's own conception of higher-risk work requiring federal review. These experiments currently fall within Section III-D of the NIH Guidelines, which demonstrates that for decades NIH has determined they can be reviewed by the local IBC. It would also be inconsistent to require federal approval here while Section IV-2 assigns research with wild-type RG3 and RG4 agents to local review.

I recommend that the Policy permit IBC review of research involving recombinant agents generated within the same family for viruses, or the same genus for bacteria and fungi, and of research involving recombinant agents where the natural source agents have assigned risk groups or recommended biosafety levels.

2.8 Federal review requires a stated reviewer, published determinations and a response timeline.

Who reviews. The Policy replaces two former categories — research requiring NIH Director approval under Section III-A of the Guidelines and research requiring NIH OSP approval under Section III-B — with a single category requiring "NIH approval," without stating which office or person performs it. Institutions can reasonably expect materially different response times from the Director and from OSP, and OSP is staffed with subject matter experts across the range of biomedical science in a way no single official can be. The Policy should state, within the responsibilities of NIH in Section III-D, who is responsible for each duty assigned to NIH, and should publish submission checklists, completeness criteria, response targets and escalation routes.

Determinations must be reusable. The Policy implies a workflow for lowering containment — an institution submits an initial request for wild-type or genetically modified RG3 or RG4 agents; NIH determines whether lower containment is appropriate; NIH publishes approved determinations; subsequent research with those agents may thereafter be approved by the IBC alone. That workflow should be stated expressly, including an unambiguous statement that once NIH has published a determination, other institutions need not obtain their own approval. This would correct a significant limitation of the current system, under which approvals extend only to a single investigator at a single institution, requiring other investigators at the same institution to seek the same determination again.

NIH should publish all containment determinations — agent, modification, approved containment and rationale — in a searchable public resource that other institutions may rely upon, not only the RG3 and RG4 lower-containment determinations Section III-D currently commits to publishing. Section III-D makes no equivalent commitment for emerging or novel agents, and it should. The Policy should state the method and minimum frequency of publication, define what constitutes substantial equivalence and which deviations are permissible, identify who determines whether a prior determination applies, and state what documentation is expected. It should also set a target response timeline — 30 calendar days would be reasonable — rather than relying on the word "timely."

Finally, the Policy should state how much information accompanies a published determination, and specifically whether publication would include security-sensitive information or unpublished data.

Risk group and containment determinations should apply broadly. Determinations of risk group and recommended biosafety level should apply to all investigators and all institutions subject to the Policy, not to the requesting investigator alone. Differences in recommended containment arising from geography, climate or research conducted outside the United States should be accounted for in implementing this change.

2.9 The three-year approval ceiling imposes burden without a stated safety benefit.

The Policy provides that approval "should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required." It does not describe how biosafety or biosecurity is improved by this limit. Research projects continue over years and decades, and they rarely incorporate changes that significantly alter the original risk assessment; those that do are already captured by the requirement to obtain approval for significant changes before implementation.

Requiring de novo submission on a fixed three-year cycle will substantially increase administrative burden for both investigators and committees for little or no gain in safety. I recommend the requirement be removed, and that the Policy instead provide for risk-based continuing review between renewals. If the requirement is retained, the Policy should expressly permit grandfathering of previously approved registrations carrying approval periods longer than three years.

3. Continued utility of Risk Groups: 3.1 Risk Groups retain utility as hazard descriptors, but should not independently determine containment or review level.

Risk Groups remain valuable tools for initial hazard communication and agent characterization, and I do not recommend that NIH abandon them. They should not, however, independently dictate either the containment level at which research is conducted or the tier at which it is reviewed. The final Policy must preserve site-specific and experiment-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities and available mitigations.

This is consistent with the draft's own Section V-E, which acknowledges that Risk Groups and Biosafety Levels are related but non-equivalent concepts. A Risk Group describes the characteristics of an agent; a Biosafety Level describes a set of containment practices, equipment and facilities. The problem is that

other provisions of the Policy do not follow Section V-E's lead, and several of them treat the two as interchangeable.

3.2 Risk Groups cannot bear the structural weight the Policy places on them.

Section IV keys multiple oversight categories directly to Risk Group — research with RG3 or RG4 wild-type agents to Section IV-2, RG2 wild-type agents and genetically modified RG1 agents to Section IV-3, and lower-containment requests to Section IV-1 depending on the agent's Risk Group. A classification system used this way must be precise, authoritative and well matched to the decision it is being asked to drive. Risk Groups are not, for several reasons:

- They describe risk to a healthy adult in the community. Section V-A states that Risk Groups reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some personnel are more susceptible because of medications, immune status or pregnancy.
- They reflect community exposure, not laboratory conditions. The concentrations, volumes and manipulations used in a laboratory differ greatly from any exposure occurring in the community or the environment.
- They provide no baseline for novel constructs. Recombinant and synthetic nucleic acid constructs do not exist in the community until they have been made and studied in a laboratory, which is the purpose of the laboratory. There is nothing for a community-based classification to describe.
- They cover only human etiologic agents. The Policy's conception of biohazards is broader than agents that cause human disease, so Risk Group cannot serve as the general basis for classifying biohazardous material.
- They are routinely misinterpreted. Investigators and federal agencies alike treat the Risk Group number as a containment requirement. This is a safety problem in both directions: it invites containment decisions that are not grounded in the actual experiment, and it substitutes a label for the assessment that should be performed.

Retained as one input to the first step of a risk assessment — characterizing the hazard — Risk Groups are useful. Used as the trigger for an oversight tier, they import all of the limitations above into a compliance determination.

3.3 The petition provision contains a condition that cannot be satisfied.

The IBC Functions provision directs the committee to petition NIH to determine the minimum biocontainment level for emerging, novel or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and prohibits IBC approval of such research until authorized by NIH and other applicable entities. This provision has two defects.

First, it treats "RG classification" and "containment level" as alternative items that might be found in the BMBL, which contradicts Section V-E's own statement that the two are non-equivalent. NIH should use these terms consistently throughout the Policy.

Second, and more consequentially: the BMBL does not assign Risk Groups. It provides agent summary

statements with recommended Biosafety Levels. A condition framed as the absence of an RG classification "in the BMBL" can never be met, because no RG classification is available there for any agent. As drafted, the provision either applies to every agent or to none, depending on how a reader resolves an error in its premise. This language requires correction.

3.4 The petition requirement is undefined as to who else must approve, and overbroad as to what it reaches.

The provision conditions IBC approval on authorization by NIH "and any other applicable Federal, State, or local entities." That phrase introduces substantial ambiguity. NIH should identify which entities are contemplated, specify whether their approvals are sequential or concurrent, state how coordination is to occur, and establish a resolution pathway for the case where determinations conflict. An institution cannot comply with a requirement to obtain approvals from an unspecified set of authorities.

The requirement is also broader than its apparent purpose. As written it can be read to apply to non-pathogenic genetically modified constructs and to benign RG1 organisms that are not specifically named in the BMBL — which is to say, most of them. NIH should state expressly that unlisted, non-pathogenic RG1 agents do not require federal petitioning. Without that clarification, the petition pathway will accumulate a backlog of submissions concerning agents that present no meaningful hazard, at the expense of the submissions that warrant federal attention.

3.5 Because Section IV depends on Risk Group assignments, the absence of an authoritative source is a structural problem.

As described in Section 1.5, Risk Group assignments have been removed from the former Appendix B of the Guidelines and do not appear in the BMBL, while the Policy continues to assign oversight tiers by Risk Group and places wild-type RG1 agents outside its scope entirely. There is presently no authoritative source for the classification on which the entire Section IV structure depends.

NIH should provide an authoritative, version-controlled federal repository of Risk Group assignments, or publish clear objective criteria by which institutions are to assign Risk Groups to non-recombinant agents, or state expressly that the local IBC holds that authority. Absent one of these, institutions will reach conflicting conclusions about the same agent, and the national consistency the Policy is intended to produce will not be achieved. Where NIH or an IBC makes a containment determination, it should apply to all investigators and institutions subject to the Policy rather than to the requesting investigator alone; Section 2.8 above addresses publication and reuse of those determinations.

The Policy should also provide a transition rule for research already under IBC approval. Many institutions have agents in active use that have no Risk Group assignment and no BMBL agent summary statement, for which the local committee has assigned a containment level based on a documented risk assessment and the published literature. NIH should state whether those determinations remain valid, whether they must be submitted for federal confirmation, and on what schedule — and it should not require that ongoing work stop pending that process.

3.6 Rigid containment minima conflict with the performance-based risk assessment the Policy otherwise requires.

The Policy requires experiment-specific risk assessment in Sections V-A through V-E, then imposes fixed containment prescriptions that override it in particular cases. Two examples warrant revision.

A universal minimum of BSL-2 for gene drive modified organisms does not map onto the specialized containment systems in which much of this work is appropriately performed — arthropod containment levels, greenhouse standards, and aquatic facilities each describe containment in terms that do not correspond to laboratory biosafety levels. NIH should permit equivalent risk-based containment modalities and issue specialized guidance for these systems rather than requiring institutions to translate an ill-fitting minimum.

Containment requirements for influenza constructs should specify the phenotypic traits, host range and pathogenicity markers that warrant enhanced containment, rather than sweeping in constructs on the basis of raw genomic segment proportions. A requirement keyed to the proportion of a genome drawn from a particular source captures constructs whose phenotype does not warrant the containment imposed, and may fail to capture constructs whose phenotype does.

3.7 Risk assessment guidance would do more to improve consistency than classification would.

If Risk Groups are to serve as one input to risk assessment rather than as a determinant of oversight, the Policy and its implementation materials should give institutions a usable method. I recommend NIH:

- State plainly how the Policy's controlling requirements and its reference guidance interact, and how differences between them are resolved.
- Permit qualified staff to support risk assessments while investigators retain their own responsibilities and the IBC independently evaluates the conclusions reached.
- Provide a concise documentation format covering likelihood, severity, exposure pathways, uncertainty, controls, residual risk and decision authority — so that an assessment can be reviewed, compared and audited.
- Publish worked examples for the categories institutions find hardest: attenuated and opportunistic agents; toxin potency, dose and form; prions and self-aggregating proteins; and validated inactivation.
- Address how short, unknown, proprietary and computationally designed sequences are to be assessed, including how encoded function, expected phenotype and residual uncertainty bear on the containment decision.
- Distinguish functional gene drives from components, split systems and intermediates, which present materially different risks and should not be treated identically.
- Clarify how influenza strain, segment and pseudotype combinations are assessed, and when a previous containment determination remains applicable to a related construct.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comments at this time.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 5.1 The effort to establish clearer federal thresholds is welcome and should be carried further.

I support the draft's effort to identify specific categories of events warranting immediate notification and follow-up reporting. Clear thresholds improve consistency across institutions and allow NIH to focus its attention on events with genuine potential public health or community significance.

The definition of a reportable incident should be refined, and the thresholds stated more precisely, so that a risk-based approach is applied consistently rather than interpreted institution by institution. The sections below identify where the current language does not yet permit that.

5.2 The Policy must define the terms on which reporting obligations depend.

The reporting provisions turn on terms the Policy does not define: incident, release, potential exposure, minor spill, improper disposition, and the distinction between basic first aid and agent-specific medical treatment. An institution cannot build a compliant reporting workflow around undefined triggers, and the result will be inconsistent practice and unintentional noncompliance rather than better information reaching NIH.

I recommend NIH adopt the following definitions in Section II:

- Incident: A confirmed theft, loss, or release — such as an occupational exposure or a release outside the defined biocontainment barriers — of biological material under the scope of the Policy.
- Release (loss of containment or occupational exposure): A failure in biosafety practice and/or equipment such that there is occupational exposure of the person or persons working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
- Potential exposure: An event occurring in the active presence of a biohazard where primary barriers or personal protective equipment were breached, creating a credible exposure pathway. Equipment or PPE failures occurring in the absence of active biohazardous agents are not potential exposures.
- Minor spill: A defined term, replacing the current formulation that minor spills "generally do not need to be reported." Subjective qualifiers such as "generally" should be removed throughout.

NIH should also align "medical treatment" explicitly with the OSHA standard — care beyond basic first aid — and state that precautionary, non-specific post-exposure prophylaxis and routine medical consultation do not constitute agent-specific treatment triggering 24-hour federal reporting. The Policy should additionally clarify how precautionary medical evaluation, prophylaxis, potential adventitious agents, and mixed or uncertain exposures bear on reportability.

5.3 The Policy should not treat maintained containment as a potential release.

The draft requires reporting of "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly." This requirement is internally contradictory. Containment at higher biosafety levels is built on layered engineering barriers precisely so that the failure of one component does not result in the escape of biological material. When redundant systems function

properly and containment is maintained, no release has occurred and none was imminent; characterizing the event as a potential release describes the system working as designed as though it had failed.

Read literally, the provision makes a spill fully contained within a biosafety cabinet a reportable event. At BSL-3, a spill outside primary containment is a breach requiring room evacuation and air clearance, and directional airflow and exhaust filtration are what prevent escape from the room — these are meaningful distinctions that the current language collapses.

I recommend NIH remove this phrasing and instead:

- Anchor "release" to containment boundaries, as defined in Section 5.2 above.
- Calibrate reporting expectations to the containment level, recognizing that higher containment incorporates redundant secondary barriers that prevent environmental dissemination even during procedural disruption.
- State that PPE or equipment failures occurring without exposure to an active agent are not reportable incidents.
- Clarify whether any event occurring at BSL-3 or BSL-4 is reportable regardless of whether it bears on biohazard containment, and distinguish equipment malfunctions where backup containment was maintained from events where containment was actually compromised.

5.4 Administrative noncompliance should be distinguished from substantive noncompliance.

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories, with no distinction drawn between kinds of noncompliance. Late paperwork, a minor recordkeeping error or a missed administrative deadline are not the same as initiating research without approval or lowering containment without authorization, and they should not be reported on the same timeline.

I recommend the Policy distinguish administrative noncompliance from substantive biosafety noncompliance, identify which violations are reportable regardless of risk and which are eligible for internal correction, and state plainly that administrative noncompliance and low-risk items never require 24-hour reporting. "Significant violations" should be defined as noncompliance that directly compromises containment or involves initiation of unapproved high-consequence research.

5.5 The reporting workflow needs mechanics institutions can actually implement.

The Policy establishes a 24-hour notification and a 30-day report without specifying how either is operated. I recommend NIH address the following, ideally in the form of a reporting decision table accompanying the template:

- Who receives the initial report, and — critically — whose awareness starts the 24-hour clock. An institution cannot demonstrate timely notification without knowing when the clock began.
- The minimum information an initial notification must contain, and how uncertainty is to be handled

when the facts are not yet established.
- When the 30-day period begins, and whether an interim report is permitted where the investigation remains incomplete at that point.
- That investigations may be conducted jointly by qualified biosafety, occupational health, clinical and veterinary personnel, with escalation to the IBC based on risk, recurrence or unresolved concerns, while preserving each body's own reporting duties. Qualified response personnel should be able to investigate and take immediate protective action without waiting for a convened meeting.

Paired worked examples would resolve most of the ambiguity at once: a contained and disinfected spill with no exposure against an event creating a credible exposure or release; an equipment malfunction with backup containment maintained against an actual containment failure; and an administrative lapse against unauthorized initiation of work. In each pairing, NIH should identify the specific facts that change the reporting pathway.

5.6 Regulatory reporting should be decoupled from public website posting.

Section III-B requires institutions to post all incident reports on a public-facing website, including reports of lower-risk incidents that are managed institutionally and are never reported to NIH. The Draft Incident Reporting Template requires identification of the Principal Investigator and does not permit redaction of the PI's name, expressly excluding the PI from the exemption that allows other involved individuals to remain unidentified, on the rationale that information available from public sources may not be redacted. I support appropriate transparency about significant biosafety incidents and institutional responses, but the disclosure requirements as drafted produce four consequences that work against the Policy's own objectives.

Personnel can be identified from posted reports. Reports containing the PI's name, the agent, the grant number and the facility location frequently provide enough detail to identify the individuals involved in an incident, even where those individuals are nominally unidentified. The information required for public posting may therefore disclose what amounts to individual medical information, with attendant legal exposure for the institution.

Identification creates personal safety risk. Linking named investigators to specific agents, funding and facility locations exposes researchers and animal care personnel to harassment, threats and targeted cyber-attacks. This concern is most acute in animal research and in other areas that have historically attracted targeting, and it applies equally to the continuously updated IBC rosters and the contact information for IBC chairs, Biological Safety Officers and committee contacts contemplated by the Biosafety Assurance.

Aggregated postings constitute a research security exposure. Publicly posted incident reports and committee minutes accumulate over time and across institutions. Taken together they would reveal which agents institutions work with, the direction of unpublished work in individual laboratories, the locations of high-containment research, and which facilities have experienced failures of equipment, training or procedure. Automated collection tools can assemble these records into a map of national high-consequence research capability. That outcome is difficult to reconcile with federal research

security policy and with the Federal Select Agent Program's own restrictions on security-sensitive information. NIH should coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, before establishing public disclosure requirements.

Posting suppresses the reporting the Policy wants to encourage. Requiring minor, fully mitigated events to appear in public view discourages internal reporting of near-misses and borderline events, out of concern for public reaction and institutional reputation. The Policy elsewhere seeks to build a safety-learning system; this provision works directly against it.

NIH should calibrate disclosure to the significance and potential public health consequence of the incident. For lower-risk incidents that do not meet federal reporting thresholds, de-identified reports, standardized summaries or aggregated reporting would provide meaningful transparency and genuine opportunity for shared learning. NIH should also state the public interest or biosafety rationale for requiring PI identification in individual reports, and consider whether that identification contributes anything to understanding or preventing incidents. As a general matter, routine public disclosure should not extend to investigator names, grant or internal project numbers, sensitive animal research information, select agent and toxin information, proprietary materials and research outcomes, identifying facility information, or other details that could compromise safety, security or personnel protection.

The better route to transparency is aggregate reporting. NIH can meet its transparency objectives by publishing aggregated, de-identified incident data — an annual incident summary with trends, contributing factors and lessons learned — and through the National Biosafety Data and Safety Analysis Center, while full records remain available to NIH and other authorized reviewers to support investigation of laboratory-acquired infections and other public health needs. A confidential national reporting system of this kind is only useful if its boundaries are clearly drawn and if institutions and investigators trust that voluntary submissions will not be used for enforcement. NIH should state expressly how confidential voluntary reporting to the NBDSAC interacts with mandatory reporting and public posting, and identify the limits of that confidentiality, so institutions can participate without uncertainty about their disclosure obligations.

5.7 If public posting is retained, redaction standards and deadlines must be specified.

Should NIH retain a public posting requirement, two elements are presently missing.

First, redaction. The Policy should permit redaction of PI names, grant identifiers, and information necessary to protect proprietary and security-sensitive material. The current formulation of "appropriate and allowable" redactions should be replaced with "specific and allowed" redactions, accompanied by standardized examples that identify what institutions may withhold on safety or security grounds. Because state public-records laws vary and may constrain what an institution is permitted to withhold, NIH guidance should distinguish the federal posting and redaction standard from any additional disclosure obligations imposed by state law.

Second, timing. The Policy ties posting to NIH's final response without defining when that response

occurs. An institution cannot be held to a posting deadline that depends on an open-ended federal review. NIH should establish a defined endpoint for its final response, and state what an institution is to do if that endpoint passes without one.

5.8 The minutes template should specify content elements rather than a format.

Institutions differ in meeting structure, recordkeeping practice, information systems, and use of software platforms that may generate meeting records or summaries automatically. A mandated template will require many institutions to maintain parallel records — one set for operations and one for compliance — without improving the information NIH or the public receives.

NIH should instead require the specific content elements needed to support transparency and accountability: review category, approval decision, containment level, and any required conditions of approval. A content-based requirement allows institutions to use their existing processes and systems while ensuring the required information is consistently documented and made available, subject to appropriate protection of sensitive information. The same flexibility should apply to the documentation format of both public meeting minutes and incident reports.

6. Other feedback relevant to this resource: 6.1 A six-month effective date is not implementable; the Policy needs at least 24 months and a phased transition.

The proposed six-month effective date is not realistic given the scope of what institutions must accomplish before covered research may continue. Within that window an institution would need to inventory all newly covered research, obtain an approved Biosafety Assurance, revise institutional policies, redesign electronic submission and records systems, build public-facing posting processes, establish redaction standards, revise incident response and reporting workflows, train investigators and committee members on requirements that do not yet exist in final form, secure institutional approvals and funding for all of it, and in some cases establish an entirely new committee.

The Assurance requirement compounds the problem. No covered research may proceed after the effective date without a written Biosafety Assurance approved by NIH. That places every institution's entire covered portfolio behind a single federal approval, submitted on roughly the same schedule as every other institution's. It is not evident that NIH will have the staff to review and approve several hundred Assurances within six months of publication, and the consequence of a backlog falls on research that is already underway and already approved locally.

I recommend NIH provide at least 24 months after publication of both the final Policy and the complete implementation materials, structured as follows:

- Phased milestones for inventory of covered research, staffing, training, systems changes, Assurance approval, and conversion of existing registrations — so that institutions can sequence the work rather than attempt all of it simultaneously.
- Provisional or deemed assurance mechanisms that prevent interruption of ongoing research where federal review is incomplete through no fault of the institution.
- Staged conversion of existing approvals. Registrations approved under the NIH Guidelines should be

permitted to convert at their next significant amendment or scheduled renewal rather than all at once, with appropriate safeguards and with priority given to higher-risk work.
- Preservation of staggered renewal cycles. Institutions have deliberately distributed renewal dates across the year. A conversion process that collapses them into a single cohort would create a backlog that persists for years and would degrade review quality for the work that most needs attention.

6.2 The templates and tools should be piloted before they become mandatory.

NIH should pilot the Biosafety Assurance, meeting minutes, incident reporting, risk assessment and delegated review tools with institutions representing a range of sizes, missions, research portfolios and program maturity. The findings should be published and used to refine the instruments for burden, clarity and usability before compliance with them is required.

This is worth the time it costs. Several of the drafting problems identified elsewhere in these comments — the reference to Risk Group classifications in the BMBL, the requirement to report failures where redundant systems maintained containment, the absence of a precedence rule between review tiers — are the kind of issue that surfaces immediately when a practitioner attempts to apply a document to a real submission, and that is difficult to see when reading it in the abstract.

6.3 The implementation resource set should be complete and available before the effective date.

The resources institutions will need include: a Biosafety Assurance template; model institutional policies; decision trees for determining review pathway and scope; risk assessment forms with worked examples; training material directed separately at committee members, biosafety staff, principal investigators and laboratory personnel; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database as described in Sections 1.5 and 2.8 above; and guidance addressing external, shared and consortium committee models.

There is also a transition-integrity question that the resource list should resolve. The NIH Guidelines carry substantial operative detail in their sections and appendices — containment specifications, laboratory practice requirements, training expectations, animal research provisions and occupational health requirements that are referenced by, but not reproduced in, the draft Policy. When the Guidelines are retired, those requirements need to land somewhere. NIH has indicated that implementation resources will draw on existing provisions, and I support preserving these risk-based protections. NIH should identify which of them remain mandatory, state whether any differ from the current Guidelines, name the authoritative document in which each will reside, and issue those materials concurrently with the final Policy and sufficiently in advance of the effective date for institutions to assess and demonstrate compliance.

6.4 NIH should publish a crosswalk between the final Policy and the requirements it replaces or overlaps.

Institutions have years of registrations, standard operating procedures, training materials and committee practice built on the section structure of the NIH Guidelines. Retiring that document without a mapping leaves every institution to independently determine which provision of the new Policy corresponds to

which provision of the old one — and they will reach different conclusions about the same question.

I recommend NIH publish a crosswalk between the final Policy, the NIH Guidelines it replaces, and other federal requirements governing research with biohazards, identifying for each area which framework governs, who owns the review, what information is shared between oversight bodies, and the applicable effective dates. This would reduce duplicative review and would give a concrete answer to the jurisdictional question raised in Section 1.7 above, rather than leaving it to be resolved institution by institution and case by case.

6.5 Two areas where additional guidance is specifically needed.

Prions and self-aggregating proteins. The Policy's definition limits this category to misfolded forms of proteins that self-propagate and cause neurodegenerative disease. That definition is reasonable, but applying it at the bench requires judgment the Policy does not support. NIH should provide practical examples and risk assessment guidance, including explicit direction on distinguishing in-scope materials from ordinary physiological protein aggregation. Without it, institutions will either over-report routine protein biochemistry or fail to identify work that genuinely falls within the category.

Computational and AI-assisted work. NIH should clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. This is a distinct question from the risk assessment of physical agents that were designed using computational or AI tools, and the two should be addressed separately. For the latter, NIH should provide practical guidance on evaluating the resulting biological hazards and on recognizing when a committee needs expertise it does not have.

6.6 The Policy should not operate as an unfunded mandate.

The draft substantially expands institutional obligations — scope of covered research, volume of review, documentation, public posting, assurance and reporting — without addressing how that work is to be resourced. Other federal regulatory agencies are required to assess the financial impact of policy changes before imposing them. In the absence of such an assessment here, NIH should address compliance cost directly.

I recommend NIH consider dedicated biosafety funding supplements; explicit statements of allowability for appropriate biosafety costs in direct or indirect cost structures; workforce development programs; shared training resources; and implementation support targeted to smaller and less-resourced institutions, for which the proportional burden of this Policy is greatest. Estimates of the additional effort NIH anticipates institutions will require would also allow institutional leadership to plan and budget rather than absorb the requirement unprepared.

6.7 The Policy should expressly permit flexible institutional arrangements.

The final Policy should state clearly that shared or consortium committees, external committee services and mutual-aid arrangements are permitted. Requirements for unaffiliated members and for specialized

expertise should be flexible enough to remain workable in small, rural or geographically isolated communities, and in communities dominated by a single institution where genuinely unaffiliated members are difficult to recruit — while still preserving meaningful independent input. Guidance addressing how these arrangements satisfy the Policy's requirements should be part of the implementation resource set.

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Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Request for Comment — NOT-OD-26-112 (August 19, 2026)

Introductory statement

RE: Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards (Request for Comment — NOT-OD-26-112, dated August 19, 2026)

To whom it may concern,

I am a principal investigator at a research-intensive academic medical center, directing a laboratory that conducts research with human respiratory viruses, including both wild-type agents and recombinant constructs, under BSL-2 and BSL-3 containment. My research is federally supported, and the work of my laboratory is reviewed and approved by my institution's Institutional Biosafety Committee under the current NIH Guidelines. I submit these comments in my individual capacity as an investigator subject to the proposed Policy. I have elected to comment anonymously, as the Notice permits.

I support the replacement of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules with risk-based biosafety oversight. The current framework is organized around a technology rather than around hazard, and after nearly fifty years it no longer maps cleanly onto how biomedical research is actually conducted. The objective NIH has set — oversight calibrated to risk, with federal attention reserved for the circumstances that warrant it and local judgment relied upon elsewhere — is the right one, and I offer these comments in support of it.

The draft Policy does not yet achieve that objective, and in its current form I do not believe it can be implemented as written. Its central difficulty is that it expands the volume of research requiring prior approval while leaving undefined many of the terms on which those approval obligations depend. The combination is what concerns me most: investigators and committees will be obligated to obtain approvals they cannot reliably identify, on a six-month timeline, with noncompliance as a term of federal funding. The predictable result is not improved biosafety but widespread unintentional noncompliance, substantial administrative effort directed at research that NIH has previously and expressly determined to be low risk, and less committee attention available for the work that genuinely warrants it.

These problems are correctable, and most of them are correctable through drafting rather than through any change in NIH's policy objectives. I respectfully request that NIH revise the Policy and publish a further draft for public comment before final issuance.

Priority recommendations

1. **Preserve the existing exemptions, or explain what changed.** The draft brings within its scope routine plasmid propagation in *E. coli* K-12, transfection of cultured cells, and BL1 transgenic rodent work — all of which the NIH Director has affirmatively determined do not present a significant risk to health or the environment. No revised risk assessment is offered. (Section 1.1, Section 2.3)
2. **Define the terms on which compliance depends.** *Biohazard*, *organism*, *vector*, *GDMO*, *adventitious agent*, *transgenic*, *incident*, *release*, *potential exposure* and *potential risk to human health* are each undefined and each load-bearing. (Sections 1.2, 5.2)
3. **Limit "genetic modification" to intentional, stable modification.** As drafted it captures serial passage, mutagenesis and selection, placing conventional virology in immediate noncompliance. (Section 1.3)
4. **Provide a review pathway for agents absent from the BMBL, and for newly identified agents.** The draft offers none for well-established agents that simply lack a BMBL entry, and for genuinely new agents it requires federal approval that depends on data the investigator cannot lawfully generate. (Sections 1.4, 2.5)
5. **Correct the petition provision in Section III-B.** It conditions IBC approval on the absence of a Risk Group classification in the BMBL. The BMBL does not assign Risk Groups, so the condition cannot be satisfied as written. (Section 3.3)
6. **Decouple incident reporting from public website posting.** Posting identifiable reports of minor, internally managed events creates personal safety and research security exposure while suppressing the near-miss reporting the Policy seeks to encourage. Aggregate, de-identified publication would serve transparency better. (Section 5.6)
7. **Allow at least 24 months, phased, and publish the implementation materials first.** Six months is not implementable, particularly given that no covered research may proceed without an NIH-approved Biosafety Assurance. (Section 6.1)

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1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

I support replacing the NIH Guidelines with risk-based biosafety oversight, and I write in support of that objective. My comments identify where the draft Policy does not yet achieve it.

1.1 The draft expands oversight of research NIH has already determined to be low risk, without explaining what changed.

NIH has described this effort as expanding oversight at the high-risk end while reducing burden for low-risk research. The second half has not been achieved. The draft brings within its scope several categories of research that are currently exempt under the NIH

Guidelines because the NIH Director affirmatively determined that they do not present a significant risk to health or the environment.

- **Propagation of recombinant plasmids in *Escherichia coli* K-12 host-vector systems**, exempt under Appendix C-II where the host carries no conjugation-proficient plasmid or generalized transducing phage and the insert derives from neither an RG3/RG4 or restricted agent nor a potent toxin. Under Section IV-3 the same work becomes "research with genetically modified RG1 biological agents" and requires approval before initiation.
- **Transfection of such a construct into a cultured mammalian cell line**, exempt since 59 FR 34472 (July 5, 1994) for recombinant molecules containing less than one-half of a eukaryotic viral genome propagated and maintained in tissue culture. Under the draft this is a genetically modified cell, which appears in Section IV-2 as full-committee work and, as a well-characterized cell line or a plasmid expressing a low-risk transgene, also in Section IV-3 as delegable. The Policy states no precedence rule, so institutions cannot determine which tier applies.
- **Breeding, transfer and use of BL1 transgenic rodents**, exempt under Appendices C-VII and C-VIII. In adopting the breeding exemption at 76 FR 3150 (January 19, 2011), NIH concluded that these experiments "do not pose an appreciable risk to human health or to the environment" and that "the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk." Generation of such lines is addressed under Section III-E-3, requiring registration at initiation but not prior approval. Section IV-3 would require prior approval for all of it.
- **Certain research with RG1 agents** not involving sequences from RG3, RG4 or restricted organisms, exempt under Appendices C-II through C-V.

The first two categories deserve particular attention because they are not marginal cases. Construction of expression plasmids and their introduction into cultured cells are the most frequently performed experimental activities in molecular biology and virology laboratories; a single project may generate dozens of constructs in a year. The draft does not state what must be registered — the backbone alone, the backbone with each insert, or each insert with each point mutation — and the answer determines whether this is an annual formality or a continuous bottleneck. Approvals also expire at three years and require de novo submission, so the burden recurs.

The draft offers no revised risk assessment for any of these categories. The cumulative-burden concern NIH identified in 2011 applies with greater force today, and with substantially greater force to routine cloning and transfection than to the rodent breeding it was written about. I ask that NIH either preserve these exemptions expressly or state what evidence supports a changed determination.

1.2 The Policy does not define the terms on which compliance depends.

The Policy is titled for research involving biohazards and does not define "biohazard." It also uses, without definition: *organism*, *transgenic*, *vector*, *GDMO*, *gene drive modified*

biological agent, *adventitious agent*, *incident*, *release*, *shedding*, *peptide*, and *potential risk to human health*. Several were also undefined in the NIH Guidelines, which makes this the right occasion to correct the problem rather than carry it forward.

"Organism" is the most consequential. It is used inconsistently and is not readily definable, and as written it leaves the relationship between Section IV-2 (genetically modified organisms) and Section IV-3 (transgenic organisms at BSL-1/ABSL-1) unresolvable, because the Policy never says how the two differ. I recommend replacing it throughout with the specific categories intended — bacteria, fungi, archaea, protists, viruses, animals — and stating expressly if there is a further category of concern, such as a biological agent produced through synthetic biology that does not fall within conventional taxonomy.

"Potential risk to human health" carries the entire scope boundary and is undefined. As written it could reach chemical, radiological or physical hazards already regulated by other federal agencies, which I do not believe NIH intends. NIH should define it as the potential to cause human disease or adverse health effects arising from the biological materials within the Policy's scope, state expressly that the Policy does not address non-biological hazards, and identify who applies the threshold and against what standard.

"Toxin" should be limited to substances of living biological origin and should exclude proteins and peptides whose primary adverse effect is an allergic or hypersensitivity response. As drafted, read together with Section IV-3's category for non-Select-Agent biological toxin proteins, the Policy reaches common laboratory reagents of biological origin.

1.3 The definition of genetic modification captures unintentional change and routine virology.

The definition includes stable alterations introduced by passaging, reassortment, or chemical or radiological means, and does not distinguish deliberate engineering from change that occurs incidentally. Serial passage of any virus in cell culture produces unintended genomic alterations; so do chemical mutagenesis, irradiation, and selection under drug pressure. Investigators performing entirely conventional work would be out of compliance immediately and without knowing it.

The definition also reaches nucleic acid molecules that "can be transcribed or translated," which includes transfection of a synthetic mRNA into a cell line. This produces an unexplained inversion: the draft removes deliberate administration of recombinant nucleic acids to human participants from the scope that Section III-C-1 of the Guidelines currently covers, while bringing transfection of the same material into cultured cells within scope. NIH should state the risk assessment supporting the conclusion that the in vitro use warrants review and the in vivo use does not.

I recommend the definition be rewritten to cover intentional, stable modification of the genome, with oversight keyed to the resulting phenotype, and that NIH address expressly how it applies to reverse genetics and viral rescue systems, including recovery of wild-type virus from cloned cDNA.

1.4 There is no review pathway for agents that lack a BMBL entry but are not emerging, novel or zoonotic.

Section IV-1 provides federal review for emerging, novel or zoonotic agents lacking an RG classification or minimum containment recommendation in the BMBL. The Policy provides nothing for the much larger set of agents that are none of those things and still have no entry. Human metapneumovirus, non-polio enteroviruses, human parainfluenza virus 5 and Sendai virus are long-established laboratory agents handled routinely at BSL-2, with no risk group in the NIH Guidelines and no BMBL agent summary statement.

Read literally, they fall into Section IV-1 and require NIH approval — an outcome that cannot be intended, given that wild-type RG3 and RG4 agents require only IBC review under Section IV-2. The same problem applies to human and animal microbiota: if research with common commensal genera requires federal review, it is not clear that an investigator can collect a human or animal specimen without entering noncompliance.

NIH should state expressly that local IBCs may perform the risk assessment and assign containment for agents in this category, reserving federal review for circumstances involving substantial uncertainty or potentially significant public or environmental consequence.

1.5 The Policy does not say who assigns risk groups.

Risk group assignment determines both the review tier and, for RG1, whether research is within scope at all — the Policy places wild-type RG1 agents outside its scope while also stating that absence from the RG2–RG4 listing does not imply classification as RG1. With Appendix B of the Guidelines retired, there is no authoritative source for these assignments and no stated authority to make them.

NIH should either publish and maintain a version-controlled list of RG1 through RG4 agents supplementing the BMBL, using Appendix B as its backbone and including RG1 agents expressly, or state in the Policy that the local IBC holds that authority. Participation by USDA, CDC and other agencies in a single list, including plant and agricultural considerations, would be valuable.

1.6 Section IV-2 operates as a catch-all with no stated boundary.

Section IV-2 requires IBC approval for initial submissions "not otherwise specified in other sections." A catch-all of that kind requires a corresponding section stating what falls outside the Policy. Institutions cannot operate from isolated bracketed notes, such as the one indicating that experiments with RG1 wild-type biological agents are not subject to the Policy. Without an express out-of-scope section, practice will vary widely between unintentional noncompliance and defensive over-review of work the Policy never meant to reach.

1.7 The relationship to other federal oversight must be stated precisely.

Section II provides that research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency once approvals or other

applicable clearances have been obtained." Section I-A-1 of the current Guidelines is narrower and clearer: another agency's approval may substitute for *NIH* review or approval. It does not displace institutional IBC oversight. The draft's broader language can be read to eliminate both, and it conflicts with the Policy's own clinical provisions, which require IBC approval in addition to all other regulatory approvals.

Concretely: an investigator registered with the Federal Select Agent Program to work with a wild-type RG4 agent needs to know whether IBC approval under Section IV-2 is still required. An investigator registered with FSAP to construct recombinant viruses in that backbone needs to know whether NIH and IBC approval are required in addition. And an institution needs to know whether an incident in high containment involving a registered Select Agent is reported to NIH and posted publicly, notwithstanding FSAP's own restrictions on security-sensitive information. NIH should state which Policy requirements survive another agency's jurisdiction, and whether approvals are sequential or concurrent.

(Implementation timing is addressed under Question 6.)

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2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs. local).

2.1 The tiered structure is the right approach, and delegated review should be made to work as intended.

The three-tier structure is a genuine improvement over the current framework, and the provision permitting delegated approval of lower-risk research — comparable to the designated member review long used by IACUCs — should meaningfully reduce the time the full committee spends on work that does not require its collective judgment. I also have no objection to bringing wild-type RG2, RG3 and RG4 biological agents within the Policy's scope. Institutions conducting that work already require IBC approval for it, and stating the requirement federally creates no new burden.

Two features of the delegated pathway undercut its purpose. First, requiring every delegated approval to be reported in full at the next convened meeting and included in publicly posted minutes recreates much of the workload the pathway exists to avoid. Institutions should be permitted to provide the committee with a concise approval log or aggregate report, with complete records retained and available for audit, and the Policy should define what role the full committee retains after a delegated approval has been granted.

Second, the Policy should make delegation under Section IV-3 optional rather than mandatory. Institutions differ in committee structure, meeting frequency and administrative capacity, and some will find full-committee review of a given category simpler than administering a delegated process for it. The Policy should also state expressly that delegated review is available for minor amendments — including amendments to research originally reviewed under Section IV-2 — and should distinguish administrative changes from changes requiring reassessment of risk.

Where delegated review is used, the Policy should specify a procedure: notice to all members of a pending review with access to the submission materials; a reasonable period, defined in written institutional procedures, within which any member may request full committee review; assignment of qualified, unconflicted member reviewers; agreement among multiple reviewers, with unresolved differences referred to the full committee; and communication of the approval to the committee for inclusion in its records.

2.2 The Policy provides no rule for resolving overlapping categories.

Sections IV-2 and IV-3 overlap substantially. Genetically modified cells, viruses and organisms appear in Section IV-2 as full-committee work, while several subsets of the same research — well-characterized cell lines, genetically modified RG1 agents, plasmids and non-integrating vectors expressing low-risk transgenes — appear in Section IV-3 as delegable. Nothing in the Policy states which controls. The same construct transfected into the same cell line can be classified in either tier depending on which sentence the reviewer reads first.

The final Policy should state expressly that the most specific applicable category controls, and should include a review-pathway decision table with worked examples spanning full committee review, delegated review, registration, exemption and NIH review. The table should resolve routine cases that will otherwise be decided inconsistently across institutions: transfection of an established cell line, use of a previously edited cell line, a change in personnel, and a change in laboratory room. A room change should not be treated as administrative without first assessing its containment implications. The Policy should also state how de novo renewals are categorized.

2.3 Several categories are placed in tiers disproportionate to their risk.

The categories identified in Section 1.1 above are not merely formerly exempt; they are placed at review levels that do not correspond to any articulated biosafety concern. The Policy does not describe how oversight of this research increases biosafety or biosecurity, and in several cases the administrative burden is substantial while the risk is negligible.

Genetically modified cells, viruses and organisms (Section IV-2). This category is misplaced and internally inconsistent. Genetic modification of cells presents very low biosafety risk absent introduction of nucleic acids from RG3 or RG4 agents or sequences encoding toxins, and such work should be at most within Section IV-3, if not exempt. The category also contains terms that are undefined or poorly defined and that conflict with other categories: as written “organism” appears to include animals notwithstanding the separate transgenic category in Section IV-3; “vector” does not distinguish viral vectors from arthropod disease vectors; and “gene drive modified biological agent” cannot be reconciled with the Policy’s own definition of biological agent, while its relationship to the undefined acronym GDMO is unstated.

I recommend this category be removed or extensively rewritten as follows:

- The definition of genetic modification should be limited to intentional stable alterations of the genome, as described in Section 1.3 above. Definitions for

organism, *vector*, *GDMO* and *gene drive modified biological agent* must be added to the Policy or the terms removed.

- Research with genetically modified RG3 and RG4 biological agents should require IBC approval.
- Research with genetically modified RG2 biological agents should be eligible for delegated approval.
- Research with gene drive modified organisms should require IBC approval.
- Review of research with genetically modified cells should depend on the modification, with pathways ranging from IBC approval through delegated approval to complete exemption from the Policy.

Research with genetically modified RG1 biological agents (Section IV-3). Certain research with RG1 agents not involving DNA from RG3, RG4 or restricted organisms is exempt under Appendices C-II through C-V, having been determined by the NIH Director not to present a significant risk to health or the environment. This category contradicts that determination without explanation. I recommend it be removed.

Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes (Section IV-3). This research is of low biosafety and biosecurity risk and the Policy does not describe how regulating it advances either. Investigators generate plasmids continuously, and requiring prior approval for them will produce a severe bottleneck and extensive unintentional noncompliance. The Policy also fails to state the extent of what must be registered — the backbone alone, the backbone with each gene to be inserted, or each gene with each mutation of that gene. I recommend this category be removed.

Research with well-characterized cell lines (Section IV-3). The Policy does not identify the biosafety concern this category addresses, nor what must be registered: that an investigator works with cell lines at all, each individual line, or whether an entire catalog may be approved at once. Registration of this work will produce extensive unintentional noncompliance and crippling administrative burden for investigators and committees alike, with no corresponding benefit. I recommend this category be removed.

Research conducted with transgenic organisms at BSL-1/ABSL-1 (Section IV-3). For the reasons given in Section 1.1, work with transgenic rodents that may be housed at ABSL-1 should not require IBC approval. I recognize that research with some transgenic animals may not yet have accumulated a comparable safety record and should continue to require approval before initiation. NIH should also consider whether transgenic fruit flies and zebrafish warrant exemption on the strength of their own track record. I recommend this category be rewritten as: *Research conducted with transgenic animals, other than transgenic rodents, fruit flies and zebrafish, that may be housed at minimum BSL-1/ABSL-1/ACL-1.* Consistent with Section 1.2, "organism" should be replaced with "animal" in this category.

Research with biological toxin proteins not on the Select Agent list (Section IV-3). Under the Policy's definition of toxin, this category reaches food and animal allergens and other common reagents of biological origin, which cannot be the intent. There is also a conflict between the category's wording and the definition itself that makes the scope

difficult to determine. Work with toxins is in many institutions already overseen by a chemical safety committee, and additional committee review will not increase safety. I recommend this category be removed. If it is retained, it should be rewritten as: *Research with biological toxin proteins with an LD_{50} in vertebrates of less than 100 micrograms per kilogram of body weight* — and the Policy should include a list of toxins classified under it, using the LD_{50} classification currently available from NIH OSP under Appendix F-1 of the Guidelines as its backbone.

Institutions should additionally be permitted to clear work in any of these categories through a documented internal screening process where that process determines the work presents minimal biosafety risk, and should retain authority to elevate work to a higher tier when local circumstances warrant.

2.4 Primary cells "that may be contaminated by adventitious agents" sits at the wrong tier and rests on an undefined term.

Section IV-2 requires full IBC approval for research with primary cells that may be contaminated by adventitious agents. The Policy does not define "adventitious agent," so institutions cannot determine what is covered. Read literally, "may be contaminated" reaches nearly all primary cell work, including cells from low-risk sources, which conflicts directly with Section IV-3's treatment of well-characterized cell lines as delegable.

The tier assignment is also inverted. Research with material that *may* contain a contaminant requires full committee review, while research with a *known* RG2 agent requires only delegated review. For clinical specimens suspected to contain higher-consequence pathogens, the BMBL recommends BSL-2 practices, containment equipment and facilities for routine handling of specimens of human or animal origin. The Policy should harmonize the level of review accordingly.

I recommend this category be removed. If it is retained: "adventitious agent" must be defined — for example, as an unintended biological agent present in cells, tissues, animals or reagents that was not deliberately introduced and is not part of the planned research; "may be contaminated" should be replaced with risk-based criteria tied to the source and screening status of the material, such as unscreened primary human or non-human primate cells; the work should not require approval where the institution complies with the OSHA Bloodborne Pathogens Standard or its equivalent; and in no case should it require more than delegated review under Section IV-3. If the intent is instead to reach primary cells potentially contaminated by any unknown biohazard, such as field samples, that should be stated and defined.

2.5 Federal review as drafted leaves no path to study a newly identified agent.

Section IV-1 requires NIH and IBC approval for research involving emerging, novel or zoonotic agents for which an RG classification or minimum containment recommendation is not available in the BMBL. For investigators whose research involves identifying previously unrecognized agents, this creates a closed loop. Once an agent is identified and found to have no assigned risk group and no BMBL recommendation, the research requires NIH approval — but without the ability to work with the agent, the investigator cannot

generate the data on which NIH would base its risk assessment. The Policy offers no route out of this.

The practical consequence is that this work will not be done in the United States. Investigators will not undertake projects that cannot be initiated, and agent discovery and characterization will shift to institutions in other countries, leaving US researchers dependent on others for the foundational characterization of agents that may later matter a great deal.

The trigger is also drawn far more broadly than the category of genuinely high-consequence uncertainty it appears aimed at. As written it captures many uncommon agents currently handled routinely at BSL-1 and BSL-2, including organisms recovered during environmental screens, and — as described in Section 1.4 — well-established agents that are simply absent from the BMBL.

I recommend the Policy describe a clear approval pathway permitting investigators to generate the data required for a risk assessment, with that review performed by the local IBC. More generally, NIH should consolidate the overlapping petition provisions, define narrowly when an emerging, novel, zoonotic or unlisted agent requires federal review, include an explicit decision rule for the case where reference information is absent, permit qualified IBCs to make interim or final containment determinations for well-characterized agents, and reserve federal preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequence.

2.6 "Emerging agent" is not a stable category and the Policy does not say who applies it.

The Policy does not state who determines that an agent is emerging. If that determination rests with the local IBC, the Policy should say so. If it does not, NIH should issue rapid dissemination notices identifying emerging agents so that institutions can avoid noncompliance with a classification they had no way to anticipate.

The Policy also does not describe how an agent ceases to be emerging. Does the designation persist until NIH first reviews the agent under Section IV-1, until a risk group is assigned, or until the agent appears in the next edition of the BMBL? Nor is it clear whether the definition reaches a well-characterized agent that exhibits a change in pathogenicity or transmission: had this Policy been in effect, it is not evident whether the recent outbreaks of Zika virus, mpox virus or Andes virus would have qualified, or whether the designation would attach to the agent or only to the specific strain. Applied today, it is not clear which agents would qualify — highly pathogenic avian influenza H5N1, or SARS-CoV-2.

These are not hypothetical distinctions. They determine whether an institution must obtain federal approval before beginning work, and an institution that guesses wrong is noncompliant.

2.7 Recombinant agents constructed within a family should be reviewable by the IBC.

The Policy's definition of novel agent captures recombinant constructs assembled from parental agents that already have assigned risk groups or recommended biosafety levels. Investigators generate such constructs routinely to study the basic biology of these agents

— exchanging a gene between two members of the same viral family, for instance, where both parents are well characterized and the containment appropriate to each is already established.

Research of this kind does not fit the Policy's own conception of higher-risk work requiring federal review. These experiments currently fall within Section III-D of the NIH Guidelines, which demonstrates that for decades NIH has determined they can be reviewed by the local IBC. It would also be inconsistent to require federal approval here while Section IV-2 assigns research with wild-type RG3 and RG4 agents to local review.

I recommend that the Policy permit IBC review of research involving recombinant agents generated within the same family for viruses, or the same genus for bacteria and fungi, and of research involving recombinant agents where the natural source agents have assigned risk groups or recommended biosafety levels.

2.8 Federal review requires a stated reviewer, published determinations and a response timeline.

Who reviews. The Policy replaces two former categories — research requiring NIH Director approval under Section III-A of the Guidelines and research requiring NIH OSP approval under Section III-B — with a single category requiring "NIH approval," without stating which office or person performs it. Institutions can reasonably expect materially different response times from the Director and from OSP, and OSP is staffed with subject matter experts across the range of biomedical science in a way no single official can be. The Policy should state, within the responsibilities of NIH in Section III-D, who is responsible for each duty assigned to NIH, and should publish submission checklists, completeness criteria, response targets and escalation routes.

Determinations must be reusable. The Policy implies a workflow for lowering containment — an institution submits an initial request for wild-type or genetically modified RG3 or RG4 agents; NIH determines whether lower containment is appropriate; NIH publishes approved determinations; subsequent research with those agents may thereafter be approved by the IBC alone. That workflow should be stated expressly, including an unambiguous statement that once NIH has published a determination, other institutions need not obtain their own approval. This would correct a significant limitation of the current system, under which approvals extend only to a single investigator at a single institution, requiring other investigators at the same institution to seek the same determination again.

NIH should publish all containment determinations — agent, modification, approved containment and rationale — in a searchable public resource that other institutions may rely upon, not only the RG3 and RG4 lower-containment determinations Section III-D currently commits to publishing. Section III-D makes no equivalent commitment for emerging or novel agents, and it should. The Policy should state the method and minimum frequency of publication, define what constitutes substantial equivalence and which deviations are permissible, identify who determines whether a prior determination applies, and state what documentation is expected. It should also set a target response timeline — 30 calendar days would be reasonable — rather than relying on the word "timely."

Finally, the Policy should state how much information accompanies a published determination, and specifically whether publication would include security-sensitive information or unpublished data.

Risk group and containment determinations should apply broadly. Determinations of risk group and recommended biosafety level should apply to all investigators and all institutions subject to the Policy, not to the requesting investigator alone. Differences in recommended containment arising from geography, climate or research conducted outside the United States should be accounted for in implementing this change.

2.9 The three-year approval ceiling imposes burden without a stated safety benefit.

The Policy provides that approval "should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required." It does not describe how biosafety or biosecurity is improved by this limit. Research projects continue over years and decades, and they rarely incorporate changes that significantly alter the original risk assessment; those that do are already captured by the requirement to obtain approval for significant changes before implementation.

Requiring de novo submission on a fixed three-year cycle will substantially increase administrative burden for both investigators and committees for little or no gain in safety. I recommend the requirement be removed, and that the Policy instead provide for risk-based continuing review between renewals. If the requirement is retained, the Policy should expressly permit grandfathering of previously approved registrations carrying approval periods longer than three years.

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3. Continued utility of Risk Groups as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels outlined in the BMBL.

3.1 Risk Groups retain utility as hazard descriptors, but should not independently determine containment or review level.

Risk Groups remain valuable tools for initial hazard communication and agent characterization, and I do not recommend that NIH abandon them. They should not, however, independently dictate either the containment level at which research is conducted or the tier at which it is reviewed. The final Policy must preserve site-specific and experiment-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities and available mitigations.

This is consistent with the draft's own Section V-E, which acknowledges that Risk Groups and Biosafety Levels are related but non-equivalent concepts. A Risk Group describes the characteristics of an agent; a Biosafety Level describes a set of containment practices, equipment and facilities. The problem is that other provisions of the Policy do not follow Section V-E's lead, and several of them treat the two as interchangeable.

3.2 Risk Groups cannot bear the structural weight the Policy places on them.

Section IV keys multiple oversight categories directly to Risk Group — research with RG3 or RG4 wild-type agents to Section IV-2, RG2 wild-type agents and genetically modified RG1 agents to Section IV-3, and lower-containment requests to Section IV-1 depending on the agent's Risk Group. A classification system used this way must be precise, authoritative and well matched to the decision it is being asked to drive. Risk Groups are not, for several reasons:

- **They describe risk to a healthy adult in the community.** Section V-A states that Risk Groups reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some personnel are more susceptible because of medications, immune status or pregnancy.
- **They reflect community exposure, not laboratory conditions.** The concentrations, volumes and manipulations used in a laboratory differ greatly from any exposure occurring in the community or the environment.
- **They provide no baseline for novel constructs.** Recombinant and synthetic nucleic acid constructs do not exist in the community until they have been made and studied in a laboratory, which is the purpose of the laboratory. There is nothing for a community-based classification to describe.
- **They cover only human etiologic agents.** The Policy's conception of biohazards is broader than agents that cause human disease, so Risk Group cannot serve as the general basis for classifying biohazardous material.
- **They are routinely misinterpreted.** Investigators and federal agencies alike treat the Risk Group number as a containment requirement. This is a safety problem in both directions: it invites containment decisions that are not grounded in the actual experiment, and it substitutes a label for the assessment that should be performed.

Retained as one input to the first step of a risk assessment — characterizing the hazard — Risk Groups are useful. Used as the trigger for an oversight tier, they import all of the limitations above into a compliance determination.

3.3 The petition provision contains a condition that cannot be satisfied.

The IBC Functions provision directs the committee to petition NIH to determine the minimum biocontainment level for emerging, novel or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and prohibits IBC approval of such research until authorized by NIH and other applicable entities. This provision has two defects.

First, it treats "RG classification" and "containment level" as alternative items that might be found in the BMBL, which contradicts Section V-E's own statement that the two are non-equivalent. NIH should use these terms consistently throughout the Policy.

Second, and more consequentially: **the BMBL does not assign Risk Groups.** It provides agent summary statements with recommended Biosafety Levels. A condition framed as the absence of an RG classification "in the BMBL" can never be met, because no RG

classification is available there for any agent. As drafted, the provision either applies to every agent or to none, depending on how a reader resolves an error in its premise. This language requires correction.

3.4 The petition requirement is undefined as to who else must approve, and overbroad as to what it reaches.

The provision conditions IBC approval on authorization by NIH "and any other applicable Federal, State, or local entities." That phrase introduces substantial ambiguity. NIH should identify which entities are contemplated, specify whether their approvals are sequential or concurrent, state how coordination is to occur, and establish a resolution pathway for the case where determinations conflict. An institution cannot comply with a requirement to obtain approvals from an unspecified set of authorities.

The requirement is also broader than its apparent purpose. As written it can be read to apply to non-pathogenic genetically modified constructs and to benign RG1 organisms that are not specifically named in the BMBL — which is to say, most of them. NIH should state expressly that unlisted, non-pathogenic RG1 agents do not require federal petitioning. Without that clarification, the petition pathway will accumulate a backlog of submissions concerning agents that present no meaningful hazard, at the expense of the submissions that warrant federal attention.

3.5 Because Section IV depends on Risk Group assignments, the absence of an authoritative source is a structural problem.

As described in Section 1.5, Risk Group assignments have been removed from the former Appendix B of the Guidelines and do not appear in the BMBL, while the Policy continues to assign oversight tiers by Risk Group and places wild-type RG1 agents outside its scope entirely. There is presently no authoritative source for the classification on which the entire Section IV structure depends.

NIH should provide an authoritative, version-controlled federal repository of Risk Group assignments, or publish clear objective criteria by which institutions are to assign Risk Groups to non-recombinant agents, or state expressly that the local IBC holds that authority. Absent one of these, institutions will reach conflicting conclusions about the same agent, and the national consistency the Policy is intended to produce will not be achieved. Where NIH or an IBC makes a containment determination, it should apply to all investigators and institutions subject to the Policy rather than to the requesting investigator alone; Section 2.8 above addresses publication and reuse of those determinations.

The Policy should also provide a transition rule for research already under IBC approval. Many institutions have agents in active use that have no Risk Group assignment and no BMBL agent summary statement, for which the local committee has assigned a containment level based on a documented risk assessment and the published literature. NIH should state whether those determinations remain valid, whether they must be submitted for federal confirmation, and on what schedule — and it should not require that ongoing work stop pending that process.

3.6 Rigid containment minima conflict with the performance-based risk assessment the Policy otherwise requires.

The Policy requires experiment-specific risk assessment in Sections V-A through V-E, then imposes fixed containment prescriptions that override it in particular cases. Two examples warrant revision.

A universal minimum of BSL-2 for gene drive modified organisms does not map onto the specialized containment systems in which much of this work is appropriately performed — arthropod containment levels, greenhouse standards, and aquatic facilities each describe containment in terms that do not correspond to laboratory biosafety levels. NIH should permit equivalent risk-based containment modalities and issue specialized guidance for these systems rather than requiring institutions to translate an ill-fitting minimum.

Containment requirements for influenza constructs should specify the phenotypic traits, host range and pathogenicity markers that warrant enhanced containment, rather than sweeping in constructs on the basis of raw genomic segment proportions. A requirement keyed to the proportion of a genome drawn from a particular source captures constructs whose phenotype does not warrant the containment imposed, and may fail to capture constructs whose phenotype does.

3.7 Risk assessment guidance would do more to improve consistency than classification would.

If Risk Groups are to serve as one input to risk assessment rather than as a determinant of oversight, the Policy and its implementation materials should give institutions a usable method. I recommend NIH:

- State plainly how the Policy's controlling requirements and its reference guidance interact, and how differences between them are resolved.
- Permit qualified staff to support risk assessments while investigators retain their own responsibilities and the IBC independently evaluates the conclusions reached.
- Provide a concise documentation format covering likelihood, severity, exposure pathways, uncertainty, controls, residual risk and decision authority — so that an assessment can be reviewed, compared and audited.
- Publish worked examples for the categories institutions find hardest: attenuated and opportunistic agents; toxin potency, dose and form; prions and self-aggregating proteins; and validated inactivation.
- Address how short, unknown, proprietary and computationally designed sequences are to be assessed, including how encoded function, expected phenotype and residual uncertainty bear on the containment decision.
- Distinguish functional gene drives from components, split systems and intermediates, which present materially different risks and should not be treated identically.
- Clarify how influenza strain, segment and pseudotype combinations are assessed, and when a previous containment determination remains applicable to a related construct.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).

No comments at this time.

5. Comments on the Draft Incident Reporting and Draft Meeting Minutes Templates.

5.1 The effort to establish clearer federal thresholds is welcome and should be carried further.

I support the draft's effort to identify specific categories of events warranting immediate notification and follow-up reporting. Clear thresholds improve consistency across institutions and allow NIH to focus its attention on events with genuine potential public health or community significance.

The definition of a reportable incident should be refined, and the thresholds stated more precisely, so that a risk-based approach is applied consistently rather than interpreted institution by institution. The sections below identify where the current language does not yet permit that.

5.2 The Policy must define the terms on which reporting obligations depend.

The reporting provisions turn on terms the Policy does not define: *incident*, *release*, *potential exposure*, *minor spill*, *improper disposition*, and the distinction between basic first aid and agent-specific medical treatment. An institution cannot build a compliant reporting workflow around undefined triggers, and the result will be inconsistent practice and unintentional noncompliance rather than better information reaching NIH.

I recommend NIH adopt the following definitions in Section II:

- **Incident:** A confirmed theft, loss, or release — such as an occupational exposure or a release outside the defined biocontainment barriers — of biological material under the scope of the Policy.
- **Release (loss of containment or occupational exposure):** A failure in biosafety practice and/or equipment such that there is occupational exposure of the person or persons working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
- **Potential exposure:** An event occurring in the active presence of a biohazard where primary barriers or personal protective equipment were breached, creating a credible exposure pathway. Equipment or PPE failures occurring in the absence of active biohazardous agents are not potential exposures.

- **Minor spill:** A defined term, replacing the current formulation that minor spills "generally do not need to be reported." Subjective qualifiers such as "generally" should be removed throughout.

NIH should also align "medical treatment" explicitly with the OSHA standard — care beyond basic first aid — and state that precautionary, non-specific post-exposure prophylaxis and routine medical consultation do not constitute agent-specific treatment triggering 24-hour federal reporting. The Policy should additionally clarify how precautionary medical evaluation, prophylaxis, potential adventitious agents, and mixed or uncertain exposures bear on reportability.

5.3 The Policy should not treat maintained containment as a potential release.

The draft requires reporting of "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly." This requirement is internally contradictory. Containment at higher biosafety levels is built on layered engineering barriers precisely so that the failure of one component does not result in the escape of biological material. When redundant systems function properly and containment is maintained, no release has occurred and none was imminent; characterizing the event as a potential release describes the system working as designed as though it had failed.

Read literally, the provision makes a spill fully contained within a biosafety cabinet a reportable event. At BSL-3, a spill outside primary containment is a breach requiring room evacuation and air clearance, and directional airflow and exhaust filtration are what prevent escape from the room — these are meaningful distinctions that the current language collapses.

I recommend NIH remove this phrasing and instead:

- Anchor "release" to containment boundaries, as defined in Section 5.2 above.
- Calibrate reporting expectations to the containment level, recognizing that higher containment incorporates redundant secondary barriers that prevent environmental dissemination even during procedural disruption.
- State that PPE or equipment failures occurring without exposure to an active agent are not reportable incidents.
- Clarify whether any event occurring at BSL-3 or BSL-4 is reportable regardless of whether it bears on biohazard containment, and distinguish equipment malfunctions where backup containment was maintained from events where containment was actually compromised.

5.4 Administrative noncompliance should be distinguished from substantive noncompliance.

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories, with no distinction drawn between kinds of noncompliance. Late paperwork, a minor recordkeeping error or a missed administrative deadline are not the same as initiating research without approval or lowering containment without authorization, and they should not be reported on the same timeline.

I recommend the Policy distinguish administrative noncompliance from substantive biosafety noncompliance, identify which violations are reportable regardless of risk and which are eligible for internal correction, and state plainly that administrative noncompliance and low-risk items never require 24-hour reporting. "Significant violations" should be defined as noncompliance that directly compromises containment or involves initiation of unapproved high-consequence research.

5.5 The reporting workflow needs mechanics institutions can actually implement.

The Policy establishes a 24-hour notification and a 30-day report without specifying how either is operated. I recommend NIH address the following, ideally in the form of a reporting decision table accompanying the template:

- Who receives the initial report, and — critically — whose awareness starts the 24-hour clock. An institution cannot demonstrate timely notification without knowing when the clock began.
- The minimum information an initial notification must contain, and how uncertainty is to be handled when the facts are not yet established.
- When the 30-day period begins, and whether an interim report is permitted where the investigation remains incomplete at that point.
- That investigations may be conducted jointly by qualified biosafety, occupational health, clinical and veterinary personnel, with escalation to the IBC based on risk, recurrence or unresolved concerns, while preserving each body's own reporting duties. Qualified response personnel should be able to investigate and take immediate protective action without waiting for a convened meeting.

Paired worked examples would resolve most of the ambiguity at once: a contained and disinfected spill with no exposure against an event creating a credible exposure or release; an equipment malfunction with backup containment maintained against an actual containment failure; and an administrative lapse against unauthorized initiation of work. In each pairing, NIH should identify the specific facts that change the reporting pathway.

5.6 Regulatory reporting should be decoupled from public website posting.

Section III-B requires institutions to post all incident reports on a public-facing website, including reports of lower-risk incidents that are managed institutionally and are never reported to NIH. The Draft Incident Reporting Template requires identification of the Principal Investigator and does not permit redaction of the PI's name, expressly excluding the PI from the exemption that allows other involved individuals to remain unidentified, on the rationale that information available from public sources may not be redacted. I support appropriate transparency about significant biosafety incidents and institutional responses, but the disclosure requirements as drafted produce four consequences that work against the Policy's own objectives.

Personnel can be identified from posted reports. Reports containing the PI's name, the agent, the grant number and the facility location frequently provide enough detail to identify the individuals involved in an incident, even where those individuals are nominally

unidentified. The information required for public posting may therefore disclose what amounts to individual medical information, with attendant legal exposure for the institution.

Identification creates personal safety risk. Linking named investigators to specific agents, funding and facility locations exposes researchers and animal care personnel to harassment, threats and targeted cyber-attacks. This concern is most acute in animal research and in other areas that have historically attracted targeting, and it applies equally to the continuously updated IBC rosters and the contact information for IBC chairs, Biological Safety Officers and committee contacts contemplated by the Biosafety Assurance.

Aggregated postings constitute a research security exposure. Publicly posted incident reports and committee minutes accumulate over time and across institutions. Taken together they would reveal which agents institutions work with, the direction of unpublished work in individual laboratories, the locations of high-containment research, and which facilities have experienced failures of equipment, training or procedure. Automated collection tools can assemble these records into a map of national high-consequence research capability. That outcome is difficult to reconcile with federal research security policy and with the Federal Select Agent Program's own restrictions on security-sensitive information. NIH should coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, before establishing public disclosure requirements.

Posting suppresses the reporting the Policy wants to encourage. Requiring minor, fully mitigated events to appear in public view discourages internal reporting of near-misses and borderline events, out of concern for public reaction and institutional reputation. The Policy elsewhere seeks to build a safety-learning system; this provision works directly against it.

NIH should calibrate disclosure to the significance and potential public health consequence of the incident. For lower-risk incidents that do not meet federal reporting thresholds, de-identified reports, standardized summaries or aggregated reporting would provide meaningful transparency and genuine opportunity for shared learning. NIH should also state the public interest or biosafety rationale for requiring PI identification in individual reports, and consider whether that identification contributes anything to understanding or preventing incidents. As a general matter, routine public disclosure should not extend to investigator names, grant or internal project numbers, sensitive animal research information, select agent and toxin information, proprietary materials and research outcomes, identifying facility information, or other details that could compromise safety, security or personnel protection.

The better route to transparency is aggregate reporting. NIH can meet its transparency objectives by publishing aggregated, de-identified incident data — an annual incident summary with trends, contributing factors and lessons learned — and through the National Biosafety Data and Safety Analysis Center, while full records remain available to NIH and other authorized reviewers to support investigation of laboratory-acquired infections and other public health needs. A confidential national reporting system of this kind is only

useful if its boundaries are clearly drawn and if institutions and investigators trust that voluntary submissions will not be used for enforcement. NIH should state expressly how confidential voluntary reporting to the NBDSAC interacts with mandatory reporting and public posting, and identify the limits of that confidentiality, so institutions can participate without uncertainty about their disclosure obligations.

5.7 If public posting is retained, redaction standards and deadlines must be specified.

Should NIH retain a public posting requirement, two elements are presently missing.

First, redaction. The Policy should permit redaction of PI names, grant identifiers, and information necessary to protect proprietary and security-sensitive material. The current formulation of "appropriate and allowable" redactions should be replaced with "specific and allowed" redactions, accompanied by standardized examples that identify what institutions may withhold on safety or security grounds. Because state public-records laws vary and may constrain what an institution is permitted to withhold, NIH guidance should distinguish the federal posting and redaction standard from any additional disclosure obligations imposed by state law.

Second, timing. The Policy ties posting to NIH's final response without defining when that response occurs. An institution cannot be held to a posting deadline that depends on an open-ended federal review. NIH should establish a defined endpoint for its final response, and state what an institution is to do if that endpoint passes without one.

5.8 The minutes template should specify content elements rather than a format.

Institutions differ in meeting structure, recordkeeping practice, information systems, and use of software platforms that may generate meeting records or summaries automatically. A mandated template will require many institutions to maintain parallel records — one set for operations and one for compliance — without improving the information NIH or the public receives.

NIH should instead require the specific content elements needed to support transparency and accountability: review category, approval decision, containment level, and any required conditions of approval. A content-based requirement allows institutions to use their existing processes and systems while ensuring the required information is consistently documented and made available, subject to appropriate protection of sensitive information. The same flexibility should apply to the documentation format of both public meeting minutes and incident reports.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

6.1 A six-month effective date is not implementable; the Policy needs at least 24 months and a phased transition.

The proposed six-month effective date is not realistic given the scope of what institutions must accomplish before covered research may continue. Within that window an institution would need to inventory all newly covered research, obtain an approved Biosafety Assurance, revise institutional policies, redesign electronic submission and records systems, build public-facing posting processes, establish redaction standards, revise incident response and reporting workflows, train investigators and committee members on requirements that do not yet exist in final form, secure institutional approvals and funding for all of it, and in some cases establish an entirely new committee.

The Assurance requirement compounds the problem. No covered research may proceed after the effective date without a written Biosafety Assurance approved by NIH. That places every institution's entire covered portfolio behind a single federal approval, submitted on roughly the same schedule as every other institution's. It is not evident that NIH will have the staff to review and approve several hundred Assurances within six months of publication, and the consequence of a backlog falls on research that is already underway and already approved locally.

I recommend NIH provide at least 24 months after publication of both the final Policy and the complete implementation materials, structured as follows:

- **Phased milestones** for inventory of covered research, staffing, training, systems changes, Assurance approval, and conversion of existing registrations — so that institutions can sequence the work rather than attempt all of it simultaneously.
- **Provisional or deemed assurance mechanisms** that prevent interruption of ongoing research where federal review is incomplete through no fault of the institution.
- **Staged conversion of existing approvals.** Registrations approved under the NIH Guidelines should be permitted to convert at their next significant amendment or scheduled renewal rather than all at once, with appropriate safeguards and with priority given to higher-risk work.
- **Preservation of staggered renewal cycles.** Institutions have deliberately distributed renewal dates across the year. A conversion process that collapses them into a single cohort would create a backlog that persists for years and would degrade review quality for the work that most needs attention.

6.2 The templates and tools should be piloted before they become mandatory.

NIH should pilot the Biosafety Assurance, meeting minutes, incident reporting, risk assessment and delegated review tools with institutions representing a range of sizes, missions, research portfolios and program maturity. The findings should be published and

used to refine the instruments for burden, clarity and usability before compliance with them is required.

This is worth the time it costs. Several of the drafting problems identified elsewhere in these comments — the reference to Risk Group classifications in the BMBL, the requirement to report failures where redundant systems maintained containment, the absence of a precedence rule between review tiers — are the kind of issue that surfaces immediately when a practitioner attempts to apply a document to a real submission, and that is difficult to see when reading it in the abstract.

6.3 The implementation resource set should be complete and available before the effective date.

The resources institutions will need include: a Biosafety Assurance template; model institutional policies; decision trees for determining review pathway and scope; risk assessment forms with worked examples; training material directed separately at committee members, biosafety staff, principal investigators and laboratory personnel; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database as described in Sections 1.5 and 2.8 above; and guidance addressing external, shared and consortium committee models.

There is also a transition-integrity question that the resource list should resolve. The NIH Guidelines carry substantial operative detail in their sections and appendices — containment specifications, laboratory practice requirements, training expectations, animal research provisions and occupational health requirements that are referenced by, but not reproduced in, the draft Policy. When the Guidelines are retired, those requirements need to land somewhere. NIH has indicated that implementation resources will draw on existing provisions, and I support preserving these risk-based protections. NIH should identify which of them remain mandatory, state whether any differ from the current Guidelines, name the authoritative document in which each will reside, and issue those materials concurrently with the final Policy and sufficiently in advance of the effective date for institutions to assess and demonstrate compliance.

6.4 NIH should publish a crosswalk between the final Policy and the requirements it replaces or overlaps.

Institutions have years of registrations, standard operating procedures, training materials and committee practice built on the section structure of the NIH Guidelines. Retiring that document without a mapping leaves every institution to independently determine which provision of the new Policy corresponds to which provision of the old one — and they will reach different conclusions about the same question.

I recommend NIH publish a crosswalk between the final Policy, the NIH Guidelines it replaces, and other federal requirements governing research with biohazards, identifying for each area which framework governs, who owns the review, what information is shared between oversight bodies, and the applicable effective dates. This would reduce duplicative review and would give a concrete answer to the jurisdictional question raised in Section 1.7 above, rather than leaving it to be resolved institution by institution and case by case.

6.5 Two areas where additional guidance is specifically needed.

Prions and self-aggregating proteins. The Policy's definition limits this category to misfolded forms of proteins that self-propagate and cause neurodegenerative disease. That definition is reasonable, but applying it at the bench requires judgment the Policy does not support. NIH should provide practical examples and risk assessment guidance, including explicit direction on distinguishing in-scope materials from ordinary physiological protein aggregation. Without it, institutions will either over-report routine protein biochemistry or fail to identify work that genuinely falls within the category.

Computational and AI-assisted work. NIH should clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. This is a distinct question from the risk assessment of physical agents that were designed using computational or AI tools, and the two should be addressed separately. For the latter, NIH should provide practical guidance on evaluating the resulting biological hazards and on recognizing when a committee needs expertise it does not have.

6.6 The Policy should not operate as an unfunded mandate.

The draft substantially expands institutional obligations — scope of covered research, volume of review, documentation, public posting, assurance and reporting — without addressing how that work is to be resourced. Other federal regulatory agencies are required to assess the financial impact of policy changes before imposing them. In the absence of such an assessment here, NIH should address compliance cost directly.

I recommend NIH consider dedicated biosafety funding supplements; explicit statements of allowability for appropriate biosafety costs in direct or indirect cost structures; workforce development programs; shared training resources; and implementation support targeted to smaller and less-resourced institutions, for which the proportional burden of this Policy is greatest. Estimates of the additional effort NIH anticipates institutions will require would also allow institutional leadership to plan and budget rather than absorb the requirement unprepared.

6.7 The Policy should expressly permit flexible institutional arrangements.

The final Policy should state clearly that shared or consortium committees, external committee services and mutual-aid arrangements are permitted. Requirements for unaffiliated members and for specialized expertise should be flexible enough to remain workable in small, rural or geographically isolated communities, and in communities dominated by a single institution where genuinely unaffiliated members are difficult to recruit — while still preserving meaningful independent input. Guidance addressing how these arrangements satisfy the Policy's requirements should be part of the implementation resource set.

Closing

I appreciate the opportunity to comment on this draft, and I want to be clear that the volume of comment above reflects engagement with the proposal rather than opposition to it. The modernization NIH has undertaken is overdue, and the structural choices in the draft — tiered review calibrated to risk, delegated approval for lower-risk work, scope organized around hazard rather than technique — are sound. What the draft needs is precision: definitions that allow an investigator to determine what applies to the work in front of them, review tiers that correspond to actual risk, and an implementation period long enough that institutions can comply rather than improvise.

The concerns raised in these comments, and those raised by the biosafety and research communities more broadly, indicate that the draft cannot be implemented in its present form. I respectfully request that NIH revise the Policy and publish an additional draft for public comment before final issuance, and I would welcome the opportunity to review and comment on that revision.

Thank you for your consideration.

284. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): bacteriology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As a research microbiologist at an academic institution, I appreciate the thought that went into updating this policy, but I would like to see more clarity around its exact boundaries. As currently written, the term 'biohazard' is not explicitly defined, which leaves uncertainty about whether risks to animal health, plant health, agriculture, or the environment are inside or outside of scope. It would be helpful if the NIH could provide clear definitions and consistent terminology for 'biological agents' and 'biomedical research' so that universities — places where NIH and non-NIH funded environmental or microbiome studies happen side-by-side—know exactly when this policy applies. Additionally, providing clear rules on how existing local IBC approvals for agents without official Risk Group assignments will be transitioned would prevent significant administrative confusion.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): One of the main stated objectives of this modernization effort is to expand oversight of higher-risk activities while simultaneously reducing unnecessary burden for low-risk research. While the draft successfully broadens oversight to include many biological hazards beyond recombinant and synthetic nucleic acid technologies, it is less clear how the proposal reduces burden for lower-risk activities. For example, while RG1 wild-type agents are excluded from review, RG1 derivatives and other low-risk materials such as plasmids and well-characterized cell lines are included. This would be counter to the goal of removing “red tape for low-risk research”, as is stated in the draft.

3. Continued utility of Risk Groups: Risk Groups remain a good baseline, but the draft's expansive definition of 'genetic modification' introduces practical challenges. By including routine laboratory processes like passaging and chemical mutagenesis, the policy risks pulling standard, low-risk RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. The NIH should distinguish deliberate genetic engineering from these routine selection methods. Grounding risk assessments in the actual resulting phenotype and practical BSL guidelines will avoid administrative fatigue and maintain investigator engagement.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): To encourage non-NIH funded institutions to voluntarily comply with the new policies, it is important to keep administrative requirements risk-proportionate and clear. When compliance is seen as an exercise for low-risk work, it can dilute the institutional cooperation needed for overseeing higher-risk research.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: While I fully support transparency and institutional learning, publicly posting complete report templates that include PI names and specific funding details may have an unintended chilling effect on laboratory safety culture. In smaller academic departments or niche fields, these specific details make it simple to identify individual researchers, raising serious privacy and personal security concerns. This level of exposure risks undermining years of institutional effort to build a strong reporting culture for near-misses and minor incidents. The NIH could better achieve its transparency goals by sharing anonymized, aggregated incident data rather than identifiable institutional records.

6. Other feedback relevant to this resource: The research community wants to be a partner in making this new oversight policy successful, but the proposed six-month implementation timeline is simply unrealistic. Redesigning electronic portals, inventorying newly covered research, establishing Biosafety Assurances, and training faculty requires significant institutional coordination. Providing a 12 to 24-month window after the final materials are published would ensure a successful transition.

285. Katie Abma

I am responding: On behalf of myself

Name: Katie Abma

Name of Organization: DePaul University

Type of Organization: Academic Institution

Role: Other

Role - Other: Environmental Health & Safety staff and member of IBC

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support the comment submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA) regarding this effort. CSHEMA's comment addresses each of the questions on this form, and appropriately reflects the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs. Thank you for your consideration and your efforts to modernize this policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

286. Marian Downing, RBP, CBSP, SM(NRCM)

I am responding: On behalf of myself

Name: Marian Downing, RBP, CBSP, SM(NRCM)

Name of Organization: Self employed Biosafety Consultant

Type of Organization: Not Applicable

Role: Other

Role - Other: IBC Community Member of 2 IBCs

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): infectious diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: ABSA-NIH-Biosafety-Policy-Comments.pdf

Description: American Biological Safety Association (ABSA) International's comments on fhe draft NIH Policy, which I endorse.

ABSA International — The Association for Biosafety and Biosecurity

Organization:	ABSA International 1200 Allanson Road, Mundelein, IL 60060 Phone: (866) 425-1365 | Email: info@absa.org | Web: www.absa.org
Date:	October 19, 2026
To:	Office of Science Policy National Institutes of Health 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892
Submission Portal:	Submitted via NIH OSP Electronic Comment Portal
Subject / Notice:	Formal Public Comments and Recommendations on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice Number: NOT-OD-26-112)

ABSA International, the Association for Biosafety and Biosecurity, is a nonprofit professional association representing biosafety and biosecurity professionals in the United States and internationally. Our membership spans academic and research institutions, government laboratories, biotechnology companies, healthcare organizations, public health agencies, and consulting practices. Members bring scientific, technical, operational, and regulatory expertise across diverse biological research and laboratory settings.

ABSA's comments reflect the practical experience of professionals responsible for translating biosafety policy into daily practice. Our members conduct risk assessments, support Institutional Biosafety Committees (IBCs), develop training and containment practices, investigate incidents, and advise institutions on compliance. They understand how policy requirements affect laboratory safety, reporting culture, institutional resources, and the conduct of research.

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public

confidence in NIH-supported science. ABSA supports NIH's efforts to strengthen biosafety oversight. We offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

***Topic to Address**: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:

    a. the nature and stability of the genomic modification;

    b. whether the modification is heritable and the potential for transmission through breeding;

    c. effects on animal health, phenotype, host range, susceptibility, or disease;

    d. potential entry into breeding or food-production systems;

    e. potential environmental release or interaction with non-research animal populations;

    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and

    g. applicable federal, state, or other regulatory oversight.

2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

  Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

ABSA International believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, ABSA International requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, ABSA International welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. ABSA International does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. ABSA International recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, ABSA International recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with ABSA's earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. ABSA International recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, ABSA International kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. ABSA International encourages NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While ABSA supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: ABSA recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

287. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): developmental neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: This policy, while potentially well-intentioned, has a major flaw in that it defines genetic modification to include "ntroduction into cells, organisms, or viruses of nucleic acid molecules that... Can be transcribed or translated". This would include mRNAs, which are the basis for dramatic advances in personalized medicine, cancer treatment, and, of course, vaccines that can be rapidly produced to prevent severe illness and reduce transmission of novel infectious pathogens. mRNAs do not change any cells genetic code (contained in their genomic DNA), they have limited lifetimes, and are not passed down to offspring. mRNA technology has the potential to revolutionize medicine, and by including in under the umbrella of "genetic modification" is not only not accurate but would severely restrict our nation's ability to lead in this area of translational research and disease treatment. Limiting researchers and clinicians ability to work on mRNAs as therapeutic tools would prevent the rapid development of new therapies for previously untreated conditions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

288. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

289. Sandy Jensen

I am responding: On behalf of myself

Name: Sandy Jensen

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Director, IBC Office

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: • The scope is defined as "all biomedical research, in lab settings, involving biohazards" and the provided definition of "Laboratory Research" encompasses clinical settings, which makes the terminology confusing. Would NIH consider clarifying whether the scope includes clinical settings?
• The new policy applies to research supported in whole or in part by NIH and to non-NIH funded research at an institution that receives any NIH funding; does this include institutions that do not receive NIH funding for research involving biohazards but receive it for other research?
• Does record retention have to be based on funding or would the NIH allow it to stand alone on the basis of IBC records?
• Why is a BSO not required for BSL2 work? Most institutions conduct BSL2 work.
• What is meant by "periodically review approved research to ensure compliance" in Section II under IBC Roles and Responsibilities? Is this intended to refer to the de novo review of a protocol every 3 years or to a "Post Approval Monitoring" type program, similar to IACUC? How does it relate to (or is it the same as) the BSO's responsibility to conduct periodic inspections?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): • I support the tiered approach to review. However, can the terminology of "Delegated Review" be changed to "Designated Review" which is familiar to the research community in the IACUC and IRB realms?
• Could NIH consider more clearly stating the authority of the IBC? There are multiple references to approval, but does the IBC also have the authority to disapprove? Request modifications in order to secure approval? Does the delegated reviewer have the same authority, or are there restrictions (e.g. cannot disapprove but must instead call for full committee review)? Codifying the IBC authority in this way would be very helpful.
• "Section IV-3. Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members" as written would treat clinical and basic research identically and prohibit the use of delegated review for clinical studies of widely used therapeutics that involve infusion of genetically-modified, long lived cell types, including the class of CAR-T therapies that have

been used to treat tens of thousands of patients. Clinical studies are conducted on products that have undergone significant biosafety evaluation already and delegated review can improve the throughput and flexibility of clinical studies, thereby lowering their aggregate costs and improving the rate of new, life-saving therapies. It is thus recommended to allow delegated review of clinical studies or at least to provide a carve out for studies that involve investigational products that are substantially similar to currently approved products.

3. Continued utility of Risk Groups: • I find the RG information in the current NIH Guidelines useful when assessing biological agent risk. This works well in tandem with biosafety level information in the BMBL.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: • Institutions should not be forced to use a specific template for the Meeting Minutes. Many institutions use electronic systems, and requiring a specific template will require substantial programming changes (which further makes a 6-month implementation time unrealistic). Instead, would NIH consider stating the elements that must be included and allow institutions to develop their own format.
• Insisting on approval no later than the next convened meeting is unrealistic. Many IBC's allow their members to request changes to the Minutes prior to voting at the next meeting, which would then mean the minutes would come back for a vote to approve during the following meeting.
• Requiring the name of the PI and Grant number is appropriate unless publicly posted; then I believe that information should be redacted. In general, I believe public posting of all incident reports is unnecessary. Instead, would NIH consider allowing institutions to describe their incident reporting procedure in the Assurance, submit the appropriate ones to NIH, and maintain internal records of all others?
• Requiring immediate reporting of incidents within 24 hours in most cases is unnecessary. Would NIH consider allowing institutions to deal with situations and then file a report that includes resolution.

6. Other feedback relevant to this resource: • Six (6) months to implement is not enough time. Not only are there hundreds of protocols to convert, but we need time to obtain an approved Assurance. I recommend at least 18 months, although 3 years would be more realistic, based on the approval period and scope of changes.
• There are references to a "Biosafety Assurance" and its general content. I would like to see a template for that and have an opportunity to comment. Will it be structured similar to an Animal Welfare Assurance and will the review of it be similar? What is meant by "Other pertinent information requested by NIH"?
• While I am not concerned with providing the information in an Assurance, I have concerns with publicly posting some of the requested information on a website. (IACUC doesn't have to do that.) Our procedures are on intranet for benefit of our investigators. Incident reports that do not have to be submitted to NIH should not need to be included, and posting incident reports in general will create a punitive atmosphere that may interfere will full reporting by PIs. Instead, including a description of our incident reporting procedure in the Assurance would provide assurance to the NIH that we have the procedure in place.
• Please clarify the terminology for "externally administered IBC" and whether each site has to have its

“own” IBC of record and “own” Biosafety Assurance. Would NIH consider instead allowing a single local IBC to service multiple local locations under a single Assurance, provided the “covered components” are stated clearly in the Assurance? Again, this approach would be similar to how Animal Welfare Assurances are handled and does not include commercial IBC’s. However, this approach would greatly reduce administrative burden for local IBC’s.

• Please provide a definition of “non-affiliated” member on the IBC. I recommend stating the same definition as is used for IACUC.

• Please define what is meant by “minor” Amendment or clarify that institutions may create their own definition by policy which would then be stated in their Biosafety Assurance.

290. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Scope.
a. Suggest NIH limit its oversight to research covered by the Policy that is supported by NIH funds.
b. Shift from a blanket, process-heavy oversight to a targeted risk-based outcome-focused oversight. Suggest the Policy require less scrutiny and paperwork for low –risk work and more scrutiny for clearly defined high-risk categories.

2. Definition of “laboratory settings.”
a. If limited to laboratory settings - does this exclude animal work that does not occur in a lab setting, and what is lab in this case (are animal rooms considered labs)? Suggest providing a definition of “laboratory setting.”

3. Definition of “biohazard.”
a. It appears that the focus of the Policy is human health. However, it is unclear throughout the Policy if it also covers any plant work (or if it is all excluded, regardless if it’s genetically modified or contains gene drive), animal pathogens (or only if they are zoonotic), cell culture work, etc.. NIH should be explicit about what the Policy covers and be consistent throughout the policy.
b. Established cell lines are mentioned under delegated review, but are not mentioned under the scope unless it would fall under one of the 4 categories in the definition of biohazard. It is unclear if a normal cell line with no additional work with items 1-4 is covered.

4. Definition of Genetic modification.
a. What is included in the chemical or radiological means of altering a genome?

5. GDMO.
a. Define and use consistently throughout the Policy.

6. “Gene drive modified biological agents, GDMOs”
a. Define the difference between these two terms and use them consistently throughout the Policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 1. Implementation period of 6 months.
a. Six months does not give institutions enough time to update software systems, create new policies, and update processes to comply with the new Policy. Suggest at least a year implementation period.

2. Cost of compliance.
a. Compliance with new policies and regulations comes with a cost to institutions – either in staffing, infrastructure, or both. Suggest that NIH consider allowing biosafety costs to be included in direct or indirect cost structures (much like allowable costs for sIRB oversight or data sharing requirements), developing resources and support for the community to assist in compliance, such as training materials, workforce development, or offering funding opportunities for biosafety-related activities.

3. Biosafety Assurance.
a. What are the expectations of what is included in the Assurance (e.g., "other pertinent information requested by NIH")?
b. Is there a template with explicit and clear instructions, such as the PHS Assurance through OLAW for animal research?
c. Who is the Assurance submitted to?
d. Who is to submit it on behalf of the institution? AOR? IBC office staff? Suggest the IBC office staff have the authority to officially submit information to NIH regarding the Assurance rather than the AOR. AOR is typically in the Grant Administration office, and not familiar with biosafety work or interfacing with the IBC office staff.
e. Is all previously approved research to stop while the Assurance is under review and before it is approved? It is unrealistic for an institution to pause all ongoing research now covered by the Policy while Assurances are reviewed. Suggest allowing ongoing research to continue.
f. Is the IBC able to do any official business or reviews while the Assurance is under review?
g. What is the expected timeline for approval from NIH? Currently it takes 6-8 weeks to update committee members on our roster with NIH.
h. Are institutions allowed to rely on other institutions with an Assurance for approval of collaborative work (e.g. subawards) or are institutions required to oversee/approve work at other institutions?

4. Petitioning NIH for determinations.
a. There are many details outlined in what information must be included about the study in petitions for determining containment or lowering containment for RG3 and RG4 agents, including who can submit the petition. However, there are none of those detailed expectations or who can submit provided for cases when an institution petitions for determining biocontainment level for novel agents. Please clarify expectations.

5. IBC Function.
a. An IBC member who has a conflict with a study should not be able to count toward quorum for any decisions made about the study. Suggest NIH clarify quorum requirements and COI expectations for committee members.
b. IBC membership requirements, specifically unaffiliated member requirements, can be especially difficult to meet in communities where the institution is the largest employer. Suggest allowing

institutions to be flexible in their IBC unaffiliated membership requirements, such that it is easier to find an unaffiliated member, yet supports external input and review (e.g., allowing retired employees to serve on the committee).
c. The use of “de novo review.” This terminology can cause confusion. Suggest NIH clarify with a clear definition or use different terminology.

6. Research that requires IBC review and approval.
a. Clarify if minor modifications to full IBC level review studies that do not alter the biological risk assessment can be reviewed by delegated review.

7. “Periodically reviewing approved research.”
a. Clarify what this means for an institution. Is this an annual continuing review? Lab inspections? Post-approval monitoring?
b. How often will approved research be required to be reviewed?
c. Define “other staff” who are able to review ongoing research. Does this mean it is not a formal IBC or IBC delegate review?
d. Suggest defining yearly review (or a specific review interval) and clearly indicate if this review is an official IBC review.
e. The CURES Act was trying to reduce administrative burden and removed the yearly review requirement on the IACUC side - but now we are adding potentially a yearly requirement for IBC? Suggest removing the annual review, if that is what is meant by “periodic review.”

8. Emergency response plans approved by the IBC.
a. Clarify expectation – is this per lab, per study, or institution-wide? Suggest clarifying the acceptance of an institution-wide emergency response plan that has been reviewed/approved by the IBC.

9. Delegated review.
a. Suggest removing the requirement of notifying the IBC when approval is granted and only require notification at the next meeting. Allow for reporting to be a log of reviewed studies as opposed to a report “in full.”
b. Clarify required actions after delegated review such as approval period, continuing review, modifications, etc.
c. Allow institutions to create their own meeting template for delegated reviews and suggest removing the requirement of posting meeting minutes from delegated reviews. Having the same requirements for delegated review as full IBC review, such as meeting minutes and posting for delegated reviews, does not reduce administrative burden on the IBC Administrators or institutions.
d. Suggest NIH follow IACUC regulations and do not require meeting minutes for delegated reviews.

10. “Risk assessment for each specific experiment”
a. Suggest clarifying if this means each project/protocol or each experiment within a protocol?

11. Meeting minutes.
a. Requiring approval of the previous meeting minutes at the subsequent meeting is unrealistic. Suggest staying silent on approval timeline.

b. Why do meeting minutes (and incident reports) need to be posted for five years? Projects are re-written according to this policy every three years so studies from that long ago would no longer even be approved. Please consider shortening this period from five to three years.

12. Training requirement.
a. Training is required of the PI and research team "on the Policy." Will standardized training modules be provided by NIH for institutions to use?
b. What needs to be included in the training?
c. How often is training required?
d. Training is mentioned in the "Responsibilities of the Institution" and "Responsibilities of the PI"; however, the training requirements differ. Please clarify.

13. Responsibilities of the institution.
a. The administrative burden of posting the required information to publicly facing websites is extensive. Suggest not requiring posting details of BSL-2 work or the trainings provided to IBC staff.

14. Responsibilities of the Institutional Biosafety Committee
a. Petitioning NIH to determine the appropriate biocontainment level for research outlined in the draft Policy, including lowering containment involving RG3 and RG4 agents, should be updated as a role of the IBC, instead of specifically the IBC Chair or BSO.

15. Responsibilities of the Biological Safety Officer (BSO).
a. Define the BSO as a required institutional role.
b. Define the BSO as the institution's designated biosafety professional responsible for leading and managing the biosafety program and providing technical biosafety oversight.
c. Clearly outline the authority of the BSO to address significant biosafety concerns that may include: suspend unsafe research activities, require corrective actions, escalate biosafety concerns to institutional leadership, access laboratories and records relevant to research under the purview of the draft Policy. Alternatively, empower the institution to delegate this responsibility to the BSO.
d. Specify core duties tied to the expanded scope of the draft Policy (modernized from IV-B-3 of the Guidelines). These may include: risk assessment and containment guidance, laboratory inspections, incident reporting and response, training and competency verification, and biological safety program oversight.
e. Standardize expectations for inspections, incident reporting, and IBC support.
f. Clarify qualifications and authority of the BSO.

16. Record retention.
a. Request clarification on how long institutions need to keep materials as that section seems confusing. For example, on the IACUC side, the requirement is three years after the close of the study.

3. Continued utility of Risk Groups: 1. NIH Responsibilities – publishing approved determinations of appropriate lower containment…for RG3 or RG4 biological agents."
a. Suggest NIH also publish appropriate containment levels for emerging, novel or zoonotic agents that are not in the BMBL so that other institutions may use the determination.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comments.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1. Meeting minute template.
a. Suggest moving "Readout of Any Projects Approved by Delegated Review" to the bottom of the template. It is currently in the middle of the review elements for a specific project.
b. The amount of information required in template is extensive. For example, the details of the study, the risk assessment, the containment level, etc., are all captured in the protocol, which IBC members have access to. Recreating this information as part of the meeting minutes is a duplication of work/an extra step when information is already included in a protocol. Additionally, the minutes are after the fact - so the project has already been approved. The minutes should focus instead on controverted issues and resolutions rather than recreating protocol information.
c. The extensive nature of the information required in the template raises concerns about the security of the US research enterprise. Providing such detailed information on public facing websites allows the information to be scooped by artificial intelligence and raises security concerns, both to the publicly named PI, the institution, and the whole of the US research enterprise.
d. The template does not appear to be ADA compliant.
e. Suggest NIH provide a list of elements the minutes must contain and allow institutions to use their own templates.

2. Reporting incidents.
a. A 24-hour reporting window is not realistic for large institutions.
b. Thirty days is not long enough to complete a full report.
c. At 30 days, is the final report required, or a full report? Please distinguish between the two as both terms are used.
d. Suggest revising the timeline requirements. Suggest an initial report and then subsequent final report from the institution when the investigation is complete, the IBC is able to review the incident and make determinations of corrective actions, much like the expectation OLAW has for reporting.
e. Noncompliance in most cases does not include "incidents that impose a significant risk to human health" and thus should not be included in the mandatory reporting requirement.
f. Define "low risk incidents" that do not require reporting to NIH.
g. Suggestion – allow incidents that do not require reporting to be handled by the institution and do not require public posting. Additionally, requiring public posting of low-risk incidents may discourage researchers from reporting incidents to the institution.
h. What are we gaining from posting incidents publicly on each institution's websites? Suggest NIH post deidentified incidents reported to them and their response on a centrally located NIH-hosted website.

6. Other feedback relevant to this resource: 1. "Thus, NIH intends to provide additional supplemental materials for the community through implementation resources. These materials will include information about IBC functions, as well as content drawn from existing information, such as biosafety considerations for research with gene drive modified organisms, Risk Group (RG) classifications (currently articulated in Appendix B of the NIH Guidelines); and additional information about requirements for containment practices, occupational health plans, and training for research with RG3 influenza viruses (currently articulated in Section III-D-7 and Appendix G-II-C-5 of the NIH Guidelines)."

a. Will there be expectations beyond the Policy included in these documents? If so, will the community be able to provide comments or feedback? Suggest allowing the community to review and comment on supplemental materials and templates.
b. When are the supplemental materials expected?

2. Risk assessments required as part of IBC review.
a. Suggest NIH provide a template institutions may use to capture information for this review.

3. Risk mitigation plans.
a. Suggest NIH provide a template institutions may use to capture information for review.

291. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Transient expression does not modify the genetic code in any way. It is not equivalent to genetic modification. It is irresponsible to conflate these two terms, because it will reduce access to transient expression or repression tools being used to build medicines and vaccines.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

292. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comment-on-the-Draft-NIH-Biosafety-Policy-for-Research-Invovlving-Biohazards_BSP.docx

Description: Letter of support for CSHEMA Recommendations

16 October 2026

SUBJECT: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Support for CSHEMA Recommendations

To Whom It May Concern:
I am writing to express support for the National Institutes of Health's (NIH) efforts to modernize biosafety oversight and establish a comprehensive, risk-based framework. I appreciate the opportunity to offer feedback on the draft policy.

As a biosafety program associate my work would be directly impacted by the proposed NIH biosafety policy. I endorse the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA). CSHEMA'S recommendations appropriately reflects the practical needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

While I support CSHEMA's comments in full, I would like to draw particular attention to several priority areas that are vital to our institution's operations:

- **Clarification of Key Definitions:** Clearly define foundational terms (e.g. biological agent, toxin, genetic modification, laboratory research, genetically modified organism (GDMO) within the policy to ensure consistent interpretation and compliance across institutions.

- **Recalibration of Public Posting:** Adjust public disclosure requirements to balance public transparency with institutional security and administrative feasibility. Public posting of incidents as drafted is likely to discourage prompt reporting. If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. Remove wording that IBC rosters must be publicly-posted.

- **Implementation Resources & National Risk Database:** Develop comprehensive guidance tools, including a national database for Risk Group and containment determinations, to foster consistent, evidence-based risk assessments.

- **24-Month Phased Transition Period:** Provide a minimum 24-month phased transition period to enable institutions to update procedures, retrain staff, and adapt administrative systems smoothly. Where appropriate, permit conversion at a significant amendment or schedule d renewal, with safeguards and priority for higher-risk work. Preserving staggered renewal cycles will help to avoid unnecessary backlogs.

Thank you for your consideration of these comments and for your commitment to advancing biosafety oversight.

293. Bridget Barker

I am responding: On behalf of myself

Name: Bridget Barker

Name of Organization: Northern Arizona University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Medical mycology; fungal pathogenesis; biosafety; Risk Group 3 fungal pathogens

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's effort to modernize biosafety oversight and agree that a contemporary framework should address biological hazards beyond recombinant and synthetic nucleic acid research. As an investigator working with Coccidioides, a Risk Group 3 fungal pathogen, I particularly support a framework that considers both wild-type pathogens and genetically modified derivatives. The policy covers wild-type biological agents that cause human disease as well as genetically modified cells and organisms, and it extends beyond NIH-funded projects to covered biomedical research conducted at institutions receiving NIH funding. This represents a substantial expansion from the current NIH Guidelines. I encourage NIH to ensure that this broadened scope is accompanied by correspondingly differentiated levels of oversight and funding support to avoid slowdown in research. Research involving a wild-type RG3 pathogen, an attenuated derivative, a targeted loss-of-function mutant, and a modification reasonably expected to increase pathogenicity may all fall within the policy, but they do not necessarily present equivalent risks. The final policy should emphasize that inclusion within its scope does not imply uniform oversight. Oversight should remain proportionate to the specific biological agent, experimental manipulation, genetic modification, route of exposure, and consequences of an accidental exposure or release.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I strongly support tiered oversight calibrated to actual risk. In particular, I support the distinction in the draft policy between research with RG3 and RG4 organisms requiring IBC review and circumstances requiring additional NIH review. For well-characterized pathogens being studied under established containment conditions, qualified institutional IBCs and biosafety professionals are best positioned to assess the specific facilities, procedures, personnel, and experimental manipulations involved. Additional federal review is most valuable where unusual uncertainty or additional risk exists. The distinction is important for genetic studies of RG3 organisms. Routine genetic modification of an RG3 organism at its established containment level should not automatically trigger federal review solely because a genetic modification has occurred. The nature and anticipated consequence of that modification are critical. A targeted gene deletion intended to determine gene function, reconstitution of that mutation, and a modification reasonably anticipated to increase pathogenicity present different risks. I support retaining local IBC

authority for genetically modified RG3 organisms when research remains at appropriate containment and does not otherwise meet criteria for additional federal oversight. The draft policy's approach of requiring NIH involvement for requests to lower containment for RG3/RG4 organisms provides a reasonable example of circumstances where federal review adds value. Clear boundaries between federal and institutional review will be critical. Ambiguity could result in different institutions sending similar experiments through different regulatory pathways, delaying research without necessarily improving biosafety.

3. Continued utility of Risk Groups: Risk Groups are useful as a baseline for risk assessment, but they should be treated as a starting point rather than as a substitute for experiment-specific risk assessment or as an automatic determination of containment. This distinction is particularly important for genetically modified pathogens. The risk associated with the parental organism provides an appropriate baseline, as recognized in the draft policy, but genetic modification may decrease risk, leave relevant risk essentially unchanged, or increase risk depending upon the biological function affected. My research involves genetic manipulation of the RG3 fungal pathogen Coccidioides. In this context, genetically modified organisms may include targeted loss-of-function mutants generated to investigate metabolism or virulence, complemented strains, mutants with altered developmental phenotypes, and other engineered strains. Classifying all such organisms solely according to the Risk Group of the parental organism does not capture the biological consequences of the modification. Conversely, reducing containment simply because a genetic alteration is predicted to attenuate an organism may also be inappropriate without adequate supporting evidence. I therefore favor an approach in which parental RG establishes the initial baseline, followed by an experiment-specific risk assessment incorporating the nature of the modification, known or anticipated phenotype, experimental manipulation, route of exposure, environmental stability, available phenotypic data, and proposed containment. RG and BSL should not be viewed as competing classification systems. Risk Group describes characteristics of the biological hazard, whereas appropriate containment must also account for how that hazard will actually be manipulated. The strongest framework would retain RG as a useful starting point while relying upon BMBL-aligned, experiment-specific risk assessment to determine appropriate containment and mitigation.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NA

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I support timely reporting and careful analysis of laboratory-acquired infections, meaningful exposures, releases, and significant containment failures. These reports provide an important opportunity to identify recurring risks and improve biosafety practice. For BSL-3 and ABSL-3 laboratories, however, reporting criteria must distinguish events that represent a potential exposure, loss of containment, or credible risk to personnel or the community from minor deviations or equipment events that remain fully contained by redundant engineering and procedural controls. The draft policy identifies multiple categories of reportable incidents at BSL-3/ABSL-3 and requires rapid notification for covered incidents. NIH should provide concrete examples distinguishing reportable incidents from events appropriately documented and addressed locally. Consistent definitions will be important both for meaningful national biosafety data and for consistency among institutions. I also support transparency in IBC oversight, but public posting of IBC minutes and incident reports presents particular concerns for high-containment pathogen research. The policy should establish clear, nationally consistent standards governing redaction of security-

sensitive facility information, personnel information, proprietary or unpublished scientific information, and information whose disclosure could itself create biosafety or biosecurity concerns. IBC minutes should communicate the basis and outcome of biosafety oversight without requiring the public disclosure of experimental or facility details unnecessary to demonstrate appropriate oversight and represents a safety risk to workers. As stated, any entity can access these records, including foreign competitors and bad actors.

6. Other feedback relevant to this resource: Implementation guidance will be critical to successful application of this policy. I particularly encourage NIH to develop scenarios involving a broad range of biological systems rather than relying predominantly on examples involving viruses or bacteria. RG3 fungal pathogens present distinct biosafety considerations involving developmental state, sporulation, environmental stability, route of exposure, animal infection models, and the phenotypic consequences of genetic modification. Coccidioides provides a particularly relevant example because modern studies increasingly combine genomics, targeted genetic manipulation, phenotypic characterization, and animal infection experiments. This pathogen is naturally growing in the environment with high genetic diversity, naturally infects thousands of US citizens every year, and is acquired through environmental exposure, not transmitted person to person. This is very different than viral or bacterial infectious agents. NIH should include fungal pathogens explicitly in its examples and engage investigators and biosafety professionals experienced with medical mycology and RG3 fungi in developing implementation materials. Fungi are distinct and non-transmissible. A policy that combines clear national standards with organism-specific scientific expertise and meaningful local risk assessment will provide stronger biosafety oversight than one relying primarily upon categorical classifications.

294. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Other

Role: Member of the Public

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Define "incident" better. Add RG definitions (especially if the RG list is being removed temporarily). Define clinical research. Take a "one health" approach, still seems focused on human and would be helpful to include human, animal and plant. Clarify whether oligonucleotides, cells, and toxins are intended to fall within the definition of biological agent. Broaden or clarify the definition of toxin, which appears limited to peptides and proteins and does not clearly address synthetic toxins (are they out of scope?) Clarify whether mycotoxins fall within the policy's definition of "toxin" and are considered biohazards under the policy. Include animal biosafety containment level (ABSL) laboratories within the definition of laboratory research. Define "organism" and clarify its boundaries relative to cells, viruses, biological agents, synthetic or minimal-cell systems, multicellular models, animals, and other engineered biological systems; include examples and exclusions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Bring back RG examples and expand to include animal and plant pathogens (rather than keeping the focus primarily on human pathogens). Risk group is a great "input" to the hazard characterization/identification part of your risk assessment. Although risk group is not all that is needed in hazard identification, it is a helpful component along with scale, physical form, environmental stability, routes of transmission, susceptible species, endemicity, and many other factors. Biosafety level is more of an output of the risk assessment, telling you how what containment level/ controls are needed to work safety with the biological material.

Clarify how synthetic nucleic acid molecules should be evaluated within the Risk Group framework, including whether they should be assigned a Risk Group or evaluated using separate risk-based criteria.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Do not require information in the report that may be deemed sensitive, such as the name of Principle Investigator as

documenting personal information may violate privacy regulations and result in under reporting.

Define 24-hour reporting (meaning 24 hours from what time? When the PI or BSO are alerted of an issue?) Consider defining as 24-hours from “confirmed “reportable event rather than just 24 hours report.

Define what a release is (may mean different things at different biosafety levels, and also within the context of biosecurity).

6. Other feedback relevant to this resource: Keep appendix K for large scale containment guidance. Currently BMBL, Appendix M states, "Appendix K of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) prescribes safety practices and containment procedures for large-scale (i.e., >10 liters per container) facilities. These guidelines can be applied to all large-scale work with biological materials (e.g., genetically modified organisms [GMO] and non-GMO, human, and animal/zoonotic pathogens). Please ensure familiarity with local regulations as these may differ from recommendations in this text." Until BMBL is updated to incorporate current appendix K information, where do we go to find large scale requirements? Is there an interim solution that can be written into NIH Guidelines until BMBL can be updated?

Why only require a BSO be on an IBC when the institution conducts research at BSL-3, BSL-4 or research involving GDMOs? Most LAIs result in BSL-2 labs, so would it not be beneficial to have a BSO evaluate BSL-2 work as well? They bring a unique risk-based perspective that a PI may not have.

At least two members who are not affiliated with the institution, other than their membership on the IBC, to represent the interest of the surrounding community with respect to health and protection of the environment - specify the qualifications or selection criteria for this role.

The policy should clarify whether IBC community members must reside within a specified distance of the site served by the IBC.

Provide for how institutions may petition NIH to assign a Risk Group to a new or emerging agent not addressed in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Provide a single, clearly identified reporting pathway to report incidents.

Clarify whether theft of biohazardous material is a reportable incident and whether biosecurity incidents are within the scope of the policy.

Please provide stakeholders an opportunity to review and comment on the next draft of the policy.

295. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Children's health

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definition of "genetic modification" as reported here is incorrect:
Genetic modification:
The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
-Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing);
or Have the potential for one or more cycles of replication in a cell;
or Can be transcribed or translated;

By definition any transient expression of a nucleic acid that "can be transcribed or translated" is not a genetic modification. Please fix this whohc might have much broader impact on many practices.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

296. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Government Agency

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Clinical research, Basic research, I am a biosafety professional

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: More containment guidance is needed from appendix B.
Terms have no definition or are poorly defined.
Biosafety language in clinical research should adhere more towards infection prevention terminology.
A One Health approach should include plant and animal research.
"Desgnated Member Review" should be explicitly defined as it is for IACUC's

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Requirements for a biosafety officer at an institution needs to be expanded beyond BSL3/4 and gene drive research. The proposed changes makes the need of a biosafety officer at an institution imperative for compliance and the role of the BSO needs to elevated in importance in the institutional safety hierarchy.

3. Continued utility of Risk Groups: The NIH requires approval of risk groups and containment, but provides no guidance in appendix B.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Posting full incident reports WILL result in hippa violations of research staff. PI and grant information should not be made public. Posting thr basic facts of a biosafety incident will accomplish the stated aim of reporting transparency.
Full and complete incident reports involving select agents will alert bad actors as to the location of these agents and constitute a security risk.
24hr reporting is poorly defined. 24hrs from what?

6. Other feedback relevant to this resource: The administrative burden proposed in these changes is an unfunded mandate.
NIH should provide direct guidance defininig risk groups and the required containements.

Insitutional requirements in designating a biosafety professional should be broadened beyond extreme containment use cases.

297. Jennifer Ramil

I am responding: On behalf of myself

Name: Jennifer Ramil

Name of Organization: Sanford Burnham Prebys

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Institutional Biosafety Committee, Safety, Research Compliance

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's efforts to expand biosafety oversight beyond recombinant and synthetic nucleic acid research to address biological hazards that may not be adequately covered under the current NIH Guidelines. However, I am concerned that the proposed scope is overly broad and is not consistently aligned with the subsequent categories of research requiring full IBC review.

In particular, the proposed definition of genetic modification includes stable genomic alterations resulting from passaging, reassortment, chemical treatment, or radiological means. These techniques are used in a wide variety of routine biomedical research activities, many of which do not meaningfully increase biological risk. When considered alongside the proposed review categories, this broad definition could substantially increase the amount of research requiring full IBC review rather than delegated review. This appears inconsistent with NIH's stated objective of reducing administrative burden for lower-risk research.

I am also concerned that the proposed requirement for IBC review of primary cells that may contain adventitious pathogens could effectively encompass most primary human and animal cell research, since the possibility of adventitious contamination cannot always be excluded. While certain primary-cell materials warrant additional oversight, routine primary-cell research should not automatically require full committee review based solely on the theoretical possibility of contamination.

I recommend that NIH clarify the scope of covered research and establish clearer, risk-based criteria that distinguish routine biological research from activities presenting meaningful biological hazards. The policy should also explicitly clarify the relationship between full committee and delegated review categories to ensure that research eligible for delegated review is not inadvertently captured by broader classifications.

Ultimately, the level of IBC oversight should be determined by the actual biological risks associated with the research, rather than the techniques used or the theoretical presence of a hazard. This approach

would allow institutions to focus their limited biosafety resources on research presenting meaningful risks while maintaining appropriate oversight of lower-risk activities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support the proposed tiered oversight framework and the concept of allowing lower-risk research to undergo delegated review while reserving full IBC and federal oversight for activities presenting greater biological hazards. However, I am concerned that the proposed review categories are not consistently calibrated to actual risk and may unintentionally increase full committee review of routine biological research.

In particular, the broad definition of genetic modification, which includes alterations resulting from passaging, reassortment, chemical treatment, or radiological means, could result in a substantial amount of lower-risk research requiring full IBC review. The proposed categories also appear to overlap, with certain genetically modified cells, viruses, and organisms potentially qualifying for both full committee and delegated review. NIH should clarify which review category takes precedence when research meets the criteria for more than one tier.

I am also concerned that requiring full committee review of primary cells that may contain adventitious pathogens could encompass most primary-cell research, regardless of whether the materials present an elevated biological risk.

From my experience as an IBC Chair, effective biosafety oversight depends on allowing institutions to evaluate the specific hazards associated with proposed research and assign an appropriate level of review. Institutional biosafety professionals and IBCs are well positioned to assess agent characteristics, experimental manipulations, containment practices, personnel training, and available institutional resources.

I recommend that NIH provide greater flexibility for delegated review and establish clearer criteria distinguishing research that requires full committee approval from research that can be appropriately reviewed at the institutional level through a delegated process. Full committee review should focus on research involving significant or increased biological hazards, while lower-risk activities should be eligible for delegated review even when they involve genetic modification or potentially infectious biological materials.

I also support retaining federal oversight for research presenting particularly significant or uncertain risks, including activities requiring NIH approval before initiation. However, routine determinations involving established agents, standard laboratory practices, and well-characterized risks should generally remain under local institutional oversight.

Expanding full committee review without a corresponding increase in biological risk will create additional administrative work for investigators, biosafety offices, and IBC members without necessarily improving laboratory safety.

The tiered framework should prioritize the biological risk of the research rather than the classification of the technique or material alone. Clearer distinctions between review categories, greater flexibility for

delegated review, and appropriate institutional discretion would help NIH achieve its goal of strengthening biosafety oversight while reducing unnecessary administrative burden.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I support NIH's efforts to standardize incident reporting and IBC meeting minutes to promote consistency, transparency, and accountability across institutions. However, I have significant concerns regarding the proposed public disclosure requirements, particularly the potential unintended consequences for institutional safety culture and the relationship between researchers and biosafety professionals.

Draft Incident Reporting Template

My greatest concern is the requirement for institutions to publicly post incident reports, including incidents that are reviewed by the IBC but do not meet the threshold for reporting to NIH.

As a biosafety professional and IBC Chair, I believe one of the most important elements of an effective biosafety program is maintaining an open, collaborative relationship with researchers. I work to foster an environment where researchers view the biosafety office as a resource and partner rather than simply a regulatory enforcement function. Researchers need to feel comfortable promptly reporting exposures, spills, procedural errors, equipment failures, near misses, and other potential safety concerns.

I am deeply concerned that requiring public disclosure of incident reports could undermine this relationship.

The proposed incident-reporting template includes the Principal Investigator's name and associated NIH grant information. Although individual laboratory personnel should not be identified, the PI's identity and funding information would generally remain publicly available. I worry that researchers may become reluctant to report incidents if they believe doing so could negatively affect their PI's reputation, research program, or future funding opportunities.

This concern is particularly relevant for graduate students, postdoctoral researchers, and other laboratory personnel who may hesitate to report an incident if they believe it could have consequences for their PI or laboratory.

I am especially concerned about requiring public disclosure of lower-risk incidents that do not warrant NIH reporting. If an institution has appropriately investigated an incident, evaluated the potential hazards, and implemented corrective actions, I question what additional biosafety benefit is achieved by publicly identifying the investigator and research program involved.

I strongly recommend that NIH establish a centralized, de-identified national biosafety incident reporting database rather than requiring institutions to publicly post individually identifiable incident reports.

Institutions could submit standardized incident reports to NIH for appropriate oversight, while NIH could maintain a publicly accessible database containing de-identified information about incident types, biological agents, contributing factors, root causes, containment failures, corrective actions, and lessons learned.

I believe this would be an incredibly valuable resource for biosafety professionals. Currently, lessons learned from laboratory incidents are often limited to the institutions where they occurred. A centralized national database would allow institutions to identify recurring problems, learn from incidents at other research institutions, and implement preventive measures based on shared experiences.

This approach would advance transparency and collective learning without creating unnecessary disincentives for researchers to report incidents.

Ultimately, we should be creating policies that encourage researchers to report more incidents, not policies that may make them think twice before contacting Safety.

Draft IBC Meeting Minutes Template

I support the use of a standardized meeting-minutes template to promote consistency in IBC documentation and ensure that committees appropriately document their risk assessments, discussions, and approval decisions.

However, I am concerned about the level of detail required in publicly accessible meeting minutes, particularly the inclusion of detailed experimental manipulations, biological agents, and protocol-specific risk assessments.

IBC members need comprehensive information to conduct meaningful risk assessments, and institutions should maintain detailed internal records documenting those assessments. However, I do not believe that all of this information needs to be included in publicly posted meeting minutes.

Requiring extensive technical details in public meeting minutes may result in disclosure of scientifically sensitive, proprietary, or preliminary research information. It may also increase administrative workload without necessarily improving public understanding of institutional biosafety oversight.

I recommend that NIH distinguish between the detailed documentation necessary for effective internal IBC review and the information necessary to demonstrate appropriate oversight to the public.

Public meeting minutes should provide sufficient information to demonstrate that the IBC evaluated the relevant hazards, established appropriate containment measures, and made an informed approval decision, without requiring unnecessary disclosure of detailed experimental information.

NIH should also provide clearer guidance regarding appropriate redactions and allow institutions reasonable discretion to protect legitimate research confidentiality and security interests.

Overall, I support standardized reporting and documentation requirements, but I encourage NIH to ensure that transparency requirements do not undermine the effectiveness of institutional biosafety programs. Transparency should promote accountability, shared learning, and improved safety practices without discouraging incident reporting or creating unnecessary administrative burdens.

6. Other feedback relevant to this resource: I appreciate NIH's efforts to provide standardized templates and implementation resources to support the transition to the proposed biosafety policy. However, given the substantial changes to the scope of covered research, IBC review requirements, incident reporting, and public disclosure obligations, I believe additional guidance and a longer implementation period will be necessary.

Implementation Timeline

I am concerned that the proposed six-month implementation period is insufficient given the magnitude of the changes. Institutions will need to revise their biosafety policies, IBC procedures, protocol registration systems, review classifications, incident-reporting processes, and public disclosure practices. Investigators, biosafety professionals, and IBC members will also need training on the new requirements.

I recommend a phased implementation period of at least 24 months, particularly for institutions with established IBC programs that will need to transition existing protocols to the new oversight framework.

Additional Guidance and Resources

I would particularly appreciate NIH providing guidance in the following areas:

1. Scope and applicability: Clear examples of research activities that fall within and outside the policy, particularly routine cell culture, primary-cell research, genetic modifications resulting from passaging or chemical/radiological treatment, and other activities that have not traditionally required IBC review.

2. Full committee versus delegated review: A decision tree or classification matrix that clearly identifies which research activities require full committee review and which are eligible for delegated review. NIH should clarify how to resolve situations where research appears to meet criteria for both categories.

3. Risk assessment and containment: Practical examples demonstrating how Risk Groups, genetic modifications, experimental manipulations, and BMBL recommendations should be considered together when determining appropriate Biosafety Levels and containment practices.

4. Transition of existing IBC protocols: Guidance on whether previously approved research must undergo immediate reclassification or review, how existing approval periods will be handled, and whether institutions may transition protocols at their next scheduled renewal.

5. Incident reporting: Clear reporting thresholds, examples distinguishing NIH-reportable incidents from incidents requiring only institutional review, and guidance on which lower-risk incidents require formal documentation. I also strongly encourage NIH to reconsider institutional public posting requirements and develop a centralized, de-identified national incident reporting database.

6. Public meeting minutes and redaction: Examples of appropriately completed public meeting minutes, including the level of risk-assessment detail expected and clear criteria for protecting sensitive research information.

7. Protocol approval and renewal: Guidance on the three-year approval requirement, including whether unchanged, lower-risk research may undergo streamlined or delegated renewal rather than a full de novo review.

I also recommend that NIH provide standardized training materials, frequently asked questions, and opportunities for institutions to submit implementation questions as the policy takes effect.

Additional Public Comment Opportunity

Given the breadth of the proposed changes and the ambiguities surrounding scope, review classifications, and public disclosure requirements, I encourage NIH to consider releasing a revised draft for an additional public comment period before finalizing the policy.

As a biosafety professional and IBC Chair, I recognize that implementation guidance must be sufficiently detailed to promote consistency across institutions while allowing flexibility for institution-specific risk assessments.

Ultimately, successful implementation should be measured by whether the policy improves biosafety oversight and allows institutions to focus their resources on meaningful biological hazards, rather than simply increasing the number of protocols, committee reviews, and administrative requirements.

298. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): allergy/immunology, autoinflammatory and immune dysregulation diseases, and clinical/translational research involving human biospecimens, patient-derived cells, molecular diagnostics, therapeutic development, registries, and non-replicating nucleic-acid or viral-vector technologies

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's goal of modernizing biosafety oversight and ensuring that oversight is appropriately aligned with scientific and technological developments. The proposed expansion from recombinant or synthetic nucleic-acid research to research involving biohazards is understandable and potentially valuable. However, the scope should be defined with sufficient precision to avoid treating biologically and operationally distinct activities as equivalent.

In particular, the definition of "genetic modification" should distinguish stable or heritable genetic alterations from transient, non-integrating, non-replicating nucleic-acid delivery and expression. As currently drafted, the definition includes nucleic-acid molecules that "can be transcribed or translated." This language could encompass transient systems such as synthetic mRNA, transient plasmid expression, siRNA-related systems, and other non-integrating platforms, even when they do not persist, replicate, integrate, alter the genome, or create a heritable change.

NIH should clarify that transient expression alone does not constitute genetic modification for purposes of this Policy when the nucleic acid:

does not integrate into or otherwise stably alter the genome;
cannot replicate or support replication;
is not maintained or propagated in the recipient cell or organism; and
does not create a meaningful biosafety hazard beyond the transient biological activity of the expressed product.
Alternatively, NIH could retain the broader definition but establish an explicit low-risk category for transient, non-integrating, non-replicating nucleic-acid systems. Such work could be subject to proportionate institutional notification or delegated review rather than full IBC review.

The scope should also clearly distinguish among:

genome editing or integrating systems;
replication-competent or potentially shedding vectors;
replication-defective, non-integrating viral vectors;
transient mRNA or nucleic-acid delivery;
well-characterized human or animal cell lines;
primary cells and tissues that may contain adventitious agents; and
clinical products administered to human participants.
The policy should avoid inadvertent gaps involving novel synthetic biology systems, engineered cell lines, gene-editing systems, replication-defective vectors, and biologic products with potential for shedding or environmental dissemination. At the same time, it should avoid imposing equivalent oversight on low-risk transient systems and high-risk systems capable of integration, replication, persistence, environmental spread, or clinically significant transmission.

A clear decision tree, with representative examples, would substantially improve consistency across institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered oversight structure is appropriate and preferable to a uniform review requirement. Oversight should be proportional to the characteristics of the biological material, the genetic modification, the experimental manipulation, the route and scale of exposure, the potential for replication or shedding, and the potential consequences of an accidental release.

The proposed division among federal NIH review, institutional IBC review, delegated IBC review, and investigator-level responsibilities is generally reasonable. However, the policy should provide more objective criteria for assigning research to each tier. Institutions and investigators need to be able to determine prospectively whether a project requires:

NIH and IBC approval;
full IBC approval;
delegated or expedited IBC review; or
documentation without prospective IBC approval.
NIH should consider a formal risk matrix that includes:

Risk Group and known pathogenicity of the parent agent;
whether the modification affects host range, tissue tropism, virulence, immune evasion, persistence, replication, or shedding;
whether the construct is integrating or non-integrating;
whether replication is competent, defective, or impossible;
the expression product and its biological activity;
route, dose, scale, and frequency of exposure;
use in humans, animals, or environmental settings;
potential for environmental persistence or dissemination; and

availability of effective prophylaxis, treatment, or containment.
The policy should also provide clear transition and grandfathering provisions for protocols already reviewed under the current NIH Guidelines. Requiring full re-review of every existing protocol could overwhelm IBCs and delay research without necessarily improving safety. Existing approvals should be recognized where the risk assessment remains substantively unchanged, with re-review triggered by material changes or at the next scheduled renewal.

Federal review should be reserved for research presenting substantial uncertainty, unusually high consequences, novel agents, or risks that cannot be adequately evaluated using existing classifications and guidance. Routine, well-characterized, low-risk research should remain at the institutional or delegated-review level.

NIH should establish expected review timelines, mechanisms for requesting clarification, and a process for resolving disagreements between NIH and an institutional IBC. The local IBC should be permitted to require more stringent controls based on local facilities, personnel, procedures, and institutional expertise.

3. Continued utility of Risk Groups: Risk Groups and Biosafety Levels serve different but complementary purposes and should both be retained.

Risk Group classifications provide a useful baseline description of the intrinsic hazards associated with an agent, including pathogenicity, transmissibility, disease severity, and availability of preventive or therapeutic measures. Biosafety Levels describe the containment practices, equipment, facilities, and operational controls needed for a particular activity.

Neither RG nor BSL should be used as a complete substitute for the other. A Risk Group classification should not automatically determine the required BSL for every experiment, and BSL alone does not adequately describe the biological hazard of an agent or genetic modification.

For genetically modified agents, the risk assessment should consider the characteristics of both the parent agent and the introduced genetic material. Relevant factors include whether the modification changes:

host range or tissue tropism;
replication competence;
virulence or pathogenicity;
toxin production;
immune evasion;
persistence or latency;
environmental stability;
shedding or transmission; or
susceptibility to available treatment or prevention.
NIH should provide a clear crosswalk showing how RG classifications, BSL/ABSL containment, genetic modifications, and experimental manipulations should be considered together. The policy should also clarify how institutions should proceed when a modified agent does not fit cleanly within an existing RG

classification or BSL recommendation.

A risk-based approach is particularly important for attenuated, replication-defective, non-integrating, or otherwise biologically restricted systems. These systems may warrant lower containment than the parental agent in some circumstances, but any reduction should be supported by data and reviewed by the IBC. Conversely, a nominally lower-RG agent may require additional controls if a modification increases biological activity, persistence, host range, or environmental risk.

The BMBL should remain an important primary reference for containment and laboratory practices, while NIH should provide additional guidance for genetic modifications and novel systems that are not adequately addressed in the BMBL. The draft policy appropriately recognizes that risk assessment must consider the characteristics of the biohazard, the manipulations, and the genetic modifications.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary compliance through education, practical tools, transparency, and recognition rather than through language that creates uncertainty or disproportionate administrative obligations.

The policy should provide a clearly defined voluntary framework for institutions and investigators conducting research outside the formal scope of the Policy, including research at non-NIH-funded institutions. This framework could include:

a voluntary biosafety assurance or institutional attestation;
model IBC policies and standard operating procedures;
access to NIH training materials;
a publicly available self-assessment checklist;
a risk-assessment template;
examples of appropriate review pathways;
access to consultation with biosafety experts; and
eligibility for voluntary submission of de-identified near-miss and incident data.
Voluntary reporting of near misses and procedural weaknesses is most likely to be successful if institutions are assured that appropriately submitted, non-negligent information will be used for learning and prevention rather than punitive enforcement. The draft policy proposes voluntary, confidential reporting of certain near misses and procedural issues to a national biosafety data center; NIH should provide clear safeguards regarding confidentiality, data de-identification, and limits on enforcement use. (grants.nih.gov)

NIH should also clarify whether voluntary adoption of the Policy by a non-NIH-funded institution creates any additional legal, reporting, or public-disclosure obligations. Institutions should be able to adopt commensurate oversight without unintentionally assuming requirements designed for NIH-funded institutions.

Voluntary compliance would be encouraged by making the framework straightforward, risk-based, and compatible with existing institutional biosafety programs and applicable federal, state, and local requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Standardized templates could improve consistency, transparency, and the quality of biosafety data. However, the templates should be designed to minimize unnecessary duplication and protect privacy, proprietary information, confidential personnel information, and sensitive security-related information.

For the incident reporting template, NIH should clearly distinguish among:

reportable incidents requiring notification to NIH;
incidents requiring institutional or IBC review but not NIH notification;
near misses and procedural deviations; and
minor spills or events that do not require formal reporting.
The template should include structured fields for:

date, location, and research activity;
biological agent or material;
Risk Group and containment level;
type and severity of exposure;
whether an environmental release occurred;
whether an infection, injury, or medical evaluation occurred;
immediate corrective actions;
institutional investigation and root-cause analysis;
corrective and preventive actions;
whether the IBC, BSO, occupational health program, IRB, IACUC, or other oversight body was notified; and
whether the incident is being reported to NIH or retained at the institutional level.
The template should not require personally identifiable health information or unnecessary details about individual employees or research participants. NIH should provide clear instructions regarding when an initial notification is due, what information may be submitted later, and how amended or final reports should be handled. The draft currently contemplates immediate notification for certain significant events, followed by a fuller report within 30 days. (grants.nih.gov)

For the meeting-minutes template, NIH should include fields for:

date and meeting type;
attendance and quorum;
conflicts of interest and recusals;
protocols reviewed;
risk assessment summary;
containment level and rationale;
required conditions or modifications;
vote or determination;
delegated reviews reported to the IBC;
incident reviews;
training or policy updates; and

identification of information redacted before public posting.
NIH should clarify what information must be publicly posted and what information may be redacted to protect privacy, proprietary interests, confidential information, and institutional or national security. The draft proposes public posting of IBC meeting minutes and incident reports, with redactions where appropriate. (grants.nih.gov)

NIH should also consider providing separate public and confidential versions of incident reports and meeting minutes. Public disclosure requirements should not discourage accurate reporting or cause institutions to omit useful safety information.

6. Other feedback relevant to this resource: Successful implementation will require detailed guidance, practical examples, and adequate transition time. NIH should publish implementation materials before the final policy becomes effective and should provide a reasonable transition period for institutions to update policies, train personnel, revise databases, and modify IBC workflows.

The following resources would be particularly valuable:

A scope and applicability decision tree

This should address wild-type agents, genetically modified cells, plasmids, mRNA, siRNA, gene-editing systems, viral vectors, replicons, cell lines, primary cells, human biospecimens, toxins, prions, and clinical products.

Clear examples of genetic modification

NIH should explicitly address transient mRNA, transient plasmid expression, non-integrating vectors, replication-defective vectors, genome editing, episomal systems, synthetic biology constructs, and engineered cell lines.

A risk-assessment worksheet

The worksheet should integrate agent characteristics, genetic modifications, experimental manipulations, host range, replication, persistence, shedding, route of exposure, scale, and available mitigation.

A crosswalk among RG, BSL/ABSL, and oversight categories

This should explain when a project requires NIH review, full IBC review, delegated review, or documentation only.

Clinical research guidance

NIH should clarify oversight for investigational products administered to humans, including products that are non-replicating and non-integrating but may transiently express a protein. Guidance should address shedding, persistence, product administration, interaction with IRB and FDA requirements, and the

endpoint at which IBC oversight may conclude.

Human biospecimen and cell-line guidance

Institutions need practical direction regarding primary human cells, adventitious agents, commercially available cell lines, patient-derived cells, organoids, and specimens obtained under clinical care.

Incident-reporting guidance

NIH should provide examples of reportable and non-reportable events, near misses, occupational exposures, minor spills, animal incidents, equipment failures, and potential laboratory-acquired infections.

Public-posting and redaction guidance

NIH should define how institutions should protect personal privacy, proprietary information, confidential medical information, and security-sensitive details while meeting transparency goals.

Transition and grandfathering guidance

Existing approvals under the current NIH Guidelines should remain valid unless the risk profile has materially changed. NIH should provide a process for updating existing protocols without requiring unnecessary full re-review.

Training and technical assistance

NIH should provide standardized training for investigators, IBC members, biosafety officers, and institutional officials, as well as a mechanism for obtaining timely answers to implementation questions.

NIH has appropriately recognized that additional resources will be needed to implement a modernized policy. The final policy should not become effective until institutions have access to sufficiently detailed guidance, templates, examples, and a workable mechanism for resolving ambiguous cases

299. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comment-on-the-Draft-NIH-Biosafety-Policy-for-Research-Invovlving-Biohazards.docx

16 October 2026

SUBJECT: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Support for CSHEMA Recommendations

To Whom It May Concern:
I am writing to express support for the National Institutes of Health's (NIH) efforts to modernize biosafety oversight and establish a comprehensive, risk-based framework. I appreciate the opportunity to offer feedback on the draft policy.

As a member of Biosafety, my work would be directly impacted by the proposed NIH biosafety policy. I endorse the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA). CSHEMA'S recommendations appropriately reflects the practical needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

While I support CSHEMA's comments in full, I would like to draw particular attention to several priority areas that are vital to our institution's operations:

- **Clarification of Key Definitions:** Clearly define foundational terms (e.g. biological agent, toxin, genetic modification, laboratory research, genetically modified organism (GDMO) within the policy to ensure consistent interpretation and compliance across institutions.

- **Recalibration of Public Posting:** Adjust public disclosure requirements to balance public transparency with institutional security and administrative feasibility. Public posting of incidents as drafted is likely to discourage prompt reporting. If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. Remove wording that IBC rosters must be publicly-posted.

- **Implementation Resources & National Risk Database:** Develop comprehensive guidance tools, including a national database for Risk Group and containment determinations, to foster consistent, evidence-based risk assessments.

- **24-Month Phased Transition Period:** Provide a minimum 24-month phased transition period to enable institutions to update procedures, retrain staff, and adapt administrative systems smoothly. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserving staggered renewal cycles will help to avoid unnecessary backlogs.

Thank you for your consideration of these comments and for your commitment to advancing biosafety oversight.

Sincerely,

Member of Biosafety

300. Boston Children's Hospital

I am responding: On behalf of myself

Name:

Name of Organization: Boston Children's Hospital

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: First, the definition of genetic modification is inaccurate. Transient expression of nucleic acids that “can be transcribed or translated” is not a genetic modification by definition, because the host's DNA is NOT modified. This new oversight would impact the use of any transient gene expression system, which are not genetic modifications, for instance transient expression of proteins for recombinant antibody expression, or mRNA delivery.
Moreover, harmless Risk Group 1 (RG1) organisms containing basic plasmids, non-pathogenic mammalian cell lines, and standard reporter genes (like GFP) are now captured under federal oversight. Expanding the scope to include safe, non-pathogenic, and well-characterized laboratory models dilutes the term "biohazard." It creates unnecessary regulatory friction for foundational work that carries zero public health risk.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposal would force historically exempt, innocuous research into a pre-initiation review pipeline. Investigators would have to submit formal protocols and wait for an IBC member or subgroup to grant permission before they can start basic work. The proposed tiered oversight introduces a clerical bottleneck for thousands of low-risk laboratories. Shifting safe research from an "exempt" status to a mandated pre-approval process will choke institutional research velocity without providing any safety benefit.

3. Continued utility of Risk Groups: Trapping of RG1 Organisms via "Genetic Modification" Definitions will force historically low-risk or non-pathogenic laboratory models into a formal compliance pipeline and create an artificial regulatory burden without any measurable gain in public biosafety. Labeling standard, innocuous cellular tools as "biohazards" dilutes the meaning of the term and distracts Institutional Biosafety Committees (IBCs) from monitoring true high-consequence pathogens. For thousands of labs using innocuous agents, shifting from an "exempt" status to requiring pre-initiation approval introduces administrative bottlenecks. This slows down basic foundational research and places an immense clerical burden on institutional staff. This policy functions as an unfunded mandate and diverts limited biomedical research dollars away from actual science and into institutional compliance machinery to track harmless materials.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Publicly posting minor, zero-risk incidents (like a standard lab mouse escaping its cage or a minor spill of a benign agent) exposes institutions to unwarranted public scrutiny, media sensationalism, and reputational damage for events that carry absolutely no public health risk.

6. Other feedback relevant to this resource: N/A

301. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As the Principal Investigator of a research laboratory who has been leading research teams for 15 years at an R1 level university in the US: The definition of 'genetic modification' should NOT include transient expression or the ability to be transcribed or translated. Transient transfection of nucleic acids is a key technique in my field that is required to visualize the microscopic changes that allow us to distinguish one stage of cancer from another. Transiently transfected material cannot self-propagate, and persists for mere hours or days. Transfected material that is transcribed and translated in cells does not pose significant biosafety risk to humans, as there is no modification to the genome of the target cells, or any other living material that the constructs come into contact with.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): NA

3. Continued utility of Risk Groups: BSL are more robust.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NA

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: NA

6. Other feedback relevant to this resource: NA

302. Eric Ako BS,DVM,IBC Chair UHawaii

I am responding: On behalf of myself

Name: Eric Ako BS,DVM,IBC Chair UHawaii

Name of Organization: University of Hawaii,IBC

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I have read and support the comments of CSHEMA, including the need to more clearly define biohazards.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered oversight is appropriate when calibrated to risk..agree
Leave Room for local IBCs to choose if higher levels of assistance are required…dont want to delay Pi s

3. Continued utility of Risk Groups: Both need to be more clearly defined

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Yes,local authority is appropriate for low risk submissions

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Yes,we would like you to provide

6. Other feedback relevant to this resource: I feel like you are already responding to CSHEMA
Yes,please provide guidance

303. Alexey J. Merz, Ph.D.

I am responding: On behalf of myself

Name: Alexey J. Merz, Ph.D.

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biochemistry and Molecular Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Although I write in my personal capacity, it is worth noting my professional qualifications. I earned my PhD in Molecular Microbiology and Immunology, I have run an NIH-funded research laboratory for most of the last 22 years, I have taught upper level Biochemistry to about 5,000 undergraduate students, and I wrote molecular genetics curriculum that is currently delivered to medical students in five US states.

I am writing to point out a basic error in the proposed policy. The proposed policy states that:

"Genetic modification" includes "The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
[…] • Can be transcribed or translated…'"

As any of my undergraduate students, graduate students, or medical students would be able to explain, genetic material is by definition *heritable.* However, many types of nucleic acids that can be introduced into cells are *not heritable.* Examples of the latter include but are not limited to: nucleotides, oligonucleotides, and their derivatives; non-replicating and non-integrating nucleic acid chains delivered by replication-deficient viruses and pseudoviruses; and non-replicating and non-integrating DNA and RNA (and derivatives) introduced by transient transfection.

The proposed definition is incorrect. It is theoretically incoherent and in practice, useless. It must be amended.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

304. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/16/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Vaccines and therapeutics

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definition of biohazards is problematic. The current definition appears to consider the introduction of mRNA (a non-heritable molecule) as a genetic modification. This is nonsensical and not appropriate for the regulations.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

305. Markus Wyss

I am responding: On behalf of myself

Name: Markus Wyss

Name of Organization: MaWyCo BioGovernance

Type of Organization: Other

Type of Organization - Other: Consultancy

Role: Other

Role - Other: Advisor

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biotechnology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Many thanks for providing the opportunity to comment on the draft NIH guidelines.
(1) The draft NIH guidelines still seem to be rooted in the thinking of the early days of genetic engineering when pretty little was known about the intrinsic risks of genetic engineering. I would strongly recommend that the NIH carefully considers appropriate wording that reflects the current state of knowledge. Examples include the following:
(a) Page 14: "Research involving GDMOs requires risk assessments that incorporate a broader scope of considerations because of GREATER UNCERTAINTY of the technology and POTENTIAL UNCERTAINTY of the impact of the newly modified organism or biological agent." This is a statement focussing entirely on the technology (and precautionary thinking), making a blanket claim that the technology per se is risky. There is ample evidence from 50 years of risk assessment that this is not the case. What we now know is that we need to focus on the properties/characteristics of the modified (micro-) organisms, independently of the technology how these changes have been achieved. Thus, please delete the references to "greater uncertainty" and "potential uncertainty". Fine to keep the "broader scope of considerations", if that is meant to express that also the safety impact of the genetic modification needs to be assessed.
(b) Page 15: "Investigators and IBCs must consider the highest RG classification of all agents that are the source of sequences included in the construct, the PERCENTAGE of the genome contributed by each parent agent [...]" The percentage is entirely irrelevant. Considering that the whole-genome sequence of microorganisms can be fully determined, the entire focus should be on the sequences of concern. They may make up a minute contribution to the total genome size, making percentages meaningless.
(c) Page 15: "During risk assessment, it must be considered that there could be potentially new or unpredictable biosafety risks associated with an organism formed through combination of sequences from a number of organisms or due to the synergistic effect of combining transgenes that results in a new phenotype." This is speculation and should be deleted or adapted. Assessing whole-genome

sequences for sequences of concern is well established. Sure, further developments in WGS assessment will be made, and assessments accordingly refined. But there is no concrete basis to include a vague call for hypothetical hazards.
(d) Page 16: "Research involving GDMOs must be conducted at a minimum of BSL-2 containment." I do not think that this should be formulated as a sine qua non. A Risk Group 2 organism can be genetically modified to eliminate or inactivate sequences/proteins of concern. Such a GDMO would probably still be called a "biological agent" subject to the NIH guidelines, but could potentially be downgraded to BSL-1.

(2) It is regrettable that the updated guidelines should only apply to NIH-funded research. Given that the field of biosafety has matured, it would be highly desirable to have guidelines which are aligned and applicable across departments and institutions (at least) in the US.

(3) Definition of genetic modification (bottom of page 4 and top of page 5): this is an outdated definition, and does not reflect the ways of genetic engineering offered by genome editing techniques. Suggestion to rework.

More detailed comments:
(a) Scope description on page 3, point 2: suggestion to make it more consistent with point 1: "Biological agents, other than plants, that have been genetically modified;"
(b) Definition of "Genetic modification" on top of page 5: "The introduction into cells, organisms [...]". Introduction may mean physical introduction which would be misleading. Induction would seem more appropriate. Suggestion to write as follows: "The induction of stable alterations in the genome of cells, organisms, or viruses, e.g. by passaging, reassortment, chemical or radiological means".
(c) Definition of National Biosafety Data and Safety Analysis Center on page 5: unclear to me what "de-identify" should mean. Add "biosafety best practices" at the end of the definition. In addition, I would suggest to delete "metascience".
(d) Definition of wild type on page 5: suggestion to replace "introduced" by "induced" (see above).
(e) The abbreviation GDMO is currently not introduced appropriately in the document.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): No comment.

3. Continued utility of Risk Groups: In my understanding and experience, Risk Groups and Biosafety Levels serve two different purposes. Risk Groups are an important starting point, guiding the further assessment of the required biosafety levels. As done so far (and hopefully in the future), case-by-case evaluation can then be applied to determine the biosafety level required for a particular strain or activity. For instance, genetic modification, targeting sequences of concern, can result in the downgrading of the biosafety level. In contrast, genetic modification, introducing sequences of concern, may require an upgrading of the biosafety level. So, as said: very useful and important to keep.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comment.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: No comment.

6. Other feedback relevant to this resource: No comment.

306. Ali Asy

I am responding: On behalf of myself

Name: Ali Asy

Name of Organization: Animal Health Research Institute

Type of Organization: Academic Institution

Role: Other

Role - Other: Professor of Pharmacology and BRM Senior Advisor

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Animal Health Research Institute

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The expanded coverage of biohazards to include all biohazards was scientifically based, as well as reflective of the current research environment, specifically the One Health concept, which includes zoonotic and environmental agent intersections.
Although the focus was primarily on human health, the exclusion of genetically modified plants and plant pathogens that are not related to human illness may create an area of risk. Genetically modified plants and plant pathogens can have a major effect upon both ecological and agricultural biosafety, particularly when there is a possibility of gene drive or release into the environment.
Therefore, I suggest that NIH develop a low-cost notification system for this type of research so that ecological risks associated with this type of research are not left totally unmonitored, regardless of whether these risks pose direct threats to human health.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The suggested tiered review process provides the right balance between being comprehensive and being efficient. By allowing low-risk reviews (such as well-characterized cell lines, RG1 modifications) to be handled by IBC subgroups, the administrative workload will decrease while maintaining the same level of safety. Additionally, the policy should provide guidance on what documentation is required by institutions to prove that their delegated reviewers have adequate biosafety knowledge. Finally, there needs to be a way to establish mutual recognition of IBC approvals in the case of international or multi-site studies to avoid having to go through duplicate review processes that could delay important research into zoonotic diseases.

3. Continued utility of Risk Groups: The RG provides a useful baseline; however, it is static in nature and provides information regarding only wild-type agents. Because genetic modifications may unpredictably change the pathogenicity, transmissibility, or host range of an agent, the RG does not adequately address the risks associated with genetically modified organisms. Therefore, I agree with the policy's mandate to evaluate both the parent agent and the potential impact of any genetic modifications. However, the final

policy needs to clearly state that BSL is the primary metric for determining containment levels. RGs should serve as the starting point for risk assessment, but the final containment determination should be made using a comprehensive risk assessment (as described in Section V) rather than using a fixed mapping from RG to BSL. This will help avoid the false sense of security that results from assuming a modified RG2 agent is always safe at BSL-2.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary adherence to the NIH policy on biosafety will be more likely to occur with incentives as opposed to mandates. The NIH could provide some form of recognition ("Biosafety Excellence") or a simplified process for submitting grant applications to those organizations that choose to adhere to the fundamental principles of the policy, regardless of whether they receive federal funding. Providing free access to the National Biosafety Data and Safety Analysis Center (NBDSAC) for voluntary incident reporting, and explicitly guaranteeing that reported information will remain private, de-identified and used only for non-punitive purposes, would encourage institutions to report incidents. Additionally, NIH-developed peer-to-peer outreach and education programs, disseminated via professional organizations, would make it easier for institutions with limited resources to implement the best practices identified in the policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The templates are an important step toward transparency and consistency, however two improvements would increase their scientific value and the burden placed on institutions.
Incident Reporting Template:
The "lay language" requirement is an appropriate way to provide transparency to the public. However, there are times when this can result in the loss of critical technical information required by NIH to assess potential risks (e.g., precise genetic changes made, parameters used for aerosolization, or how containment systems may fail). I would suggest a two-part format: a lay summary available to the public and a technical annex that would be reviewed by NIH. If necessary, the technical annex could be labeled as confidential. This approach will allow us to achieve both transparency and maintain a high standard of scientific integrity.
The template should have a section where you can verify if institutional corrective actions were taken (e.g., when the BSO signed off or when there was a follow-up inspection). This is so that root cause analysis doesn't result in an endless series of deadlines, but instead results in completed, closed-loop corrective action. This supports the policy's emphasis on responsibility.
IBC Meeting Minutes Template:
While the template provides a comprehensive review, it may become too complex to use for delegating approvals that are routine, such as well-characterized cell lines and modifications to RG1. I would recommend using a simplified version of a consent agenda format when delegating low-risk approvals. This will allow for the continued transparency that is required, but will reduce the burden on administrators. Higher-risk or new protocols should receive more detailed narrative documentation.
The template used for reviewing gene drive modified organism (GDMO) applications must specifically state that the review process must include a justification of the ecological risk assessment rationale, which includes the documentation of off-target effects, the persistence of the organism in the environment, and the modeling assumptions, as all three of these areas represent highly uncertain issues that require greater transparency from the public, as well as an articulation of the IBC's reasoning.

6. Other feedback relevant to this resource: Additional guidance is needed in two areas: (1) emerging and zoonotic agents: The policy requires NIH approval for agents with no BMBL RG classification; however, the time frame for NIH approval is unknown. To prevent delays in conducting research related to outbreak response, it is necessary to establish an expedited review process (such as 30-60 days). (2) Gene drive modified organisms (GDMOs): Although the policy states that GDMOs require at least BSL-2 containment, the criteria used to assess ecological risks associated with GDMOs are currently unclear. NIH must develop a systematic decision tree or risk assessment matrix for GDMOs, which would include information on how to model potential off-target effects and persistence in the environment. This will allow IBCs to consistently make assessments of these uncertain projects.

Uploaded File: NIH-Guideline-Comments.docx

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

The expanded coverage of biohazards to include all biohazards was scientifically based, as well as reflective of the current research environment, specifically the One Health concept which includes zoonotic and environmental agent intersections.

Although the focus was primarily on human health, the exclusion of genetically modified plants and plant pathogens that are not related to human illness may create an area of risk. Genetically modified plants and plant pathogens can have a major effect upon both ecological and agricultural biosafety, particularly when there is a possibility of gene drive or release into the environment.

Therefore, I suggest that NIH develop a low-cost, notification system for this type of research so that ecological risks associated with this type of research are not left totally unmonitored; regardless of whether these risks pose direct threats to human health.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).

The suggested tiered review process provides the right balance between being comprehensive and being efficient. By allowing low-risk reviews (such as well characterized cell lines, RG1 modifications) to be handled by IBC subgroups, the administrative workload will decrease, while maintaining the same level of safety. Additionally, the policy should provide guidance on what documentation is required by institutions to prove that their delegated reviewers have adequate biosafety knowledge. Finally, there needs to be a way to establish mutual recognition of IBC approvals in the case of international or multi-site studies to avoid having to go through duplicate review processes that could delay important research into zoonotic diseases.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

The RG provides a useful baseline; however, it is static in nature and provides information regarding only wild-type agents. Because genetic modifications may unpredictably change the pathogenicity, transmissibility, or host range of an agent, the RG does not adequately address the risks associated with genetically modified organisms. Therefore, I agree with the policy's mandate to evaluate both the parent agent and the potential impact of any genetic modifications. However, the final policy needs to clearly state that BSL is the primary metric for determining containment levels. RGs should serve as the starting point for risk assessment, but the final containment determination should be made using a comprehensive risk assessment (as described in Section V) rather than using a fixed mapping from RG to BSL. This will help avoid the false sense of security that results from assuming a modified RG2 agent is always safe at BSL-2.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).

Voluntary adherence to the NIH policy on biosafety will be more likely to occur with incentives as opposed to mandates. The NIH could provide some form of recognition ("Biosafety Excellence") or a simplified process for submitting grant applications to those organizations which choose to adhere to the fundamental principles of the policy, regardless of whether they receive federal funding. Providing free access to the National Biosafety Data and Safety Analysis Center (NBDSAC) for voluntary incident reporting, and explicitly guaranteeing that reported information will remain private, de-identified and used only for non-punitive purposes, would encourage institutions to report incidents. Additionally, NIH-developed peer-to-peer outreach and education programs, disseminated via professional organizations, would make it easier for institutions with limited resources to implement the best practices identified in the policy.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.

The templates are an important step toward transparency and consistency, however two improvements would increase their scientific value and the burden placed on institutions.

Incident Reporting Template:

The "lay language" requirement is an appropriate way to provide transparency to the public. However, there are times when this can result in the loss of critical technical information required by NIH to assess potential risks (e.g., precise genetic changes made, parameters used for aerosolization, or how containment systems may fail). I would suggest a two-part format: a lay summary available to the public and a technical annex that would be reviewed by NIH. If necessary, the technical annex could be labeled as confidential. This approach will allow us to achieve both transparency and maintain a high standard of scientific integrity.

The template should have a section where you can verify if institutional corrective actions were taken (e.g., when the BSO signed off or when there was a follow-up inspection). This is so that root cause analysis doesn't result in an endless series of deadlines, but instead results in completed, closed-loop corrective action. This supports the policy's emphasis on responsibility.

IBC Meeting Minutes Template:

While the template provides a comprehensive review, it may become too complex to use for delegating approvals that are routine, such as well characterized cell lines and modifications to RG1. I would recommend using a simplified version of a consent agenda format when delegating low-risk approvals. This will allow for the continued transparency that is required, but will reduce the burden on administrators. Higher risk or new protocols should receive a more detailed narrative documentation.

The template used for reviewing gene drive modified organism (GDMO) applications must specifically state that the review process must include a justification of the ecological risk assessment rationale, which includes the documentation of off-target effects, the persistence of the organism in the environment, and the modeling assumptions, as all three of these areas represent highly uncertain issues that require greater transparency from the public, as well as an articulation of the IBC's reasoning.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Additional guidance is needed in two areas: (1) emerging and zoonotic agents: The policy requires NIH approval for agents with no BMBL RG classification; however, the time frame for NIH approval is unknown. To prevent delays in conducting research related to outbreak response, it is necessary to establish an expedited review process (such as 30-60 days). (2) gene drive modified organisms (GDMOs): Although the policy states that GDMOs require at least BSL-2 containment, the criteria used to assess ecological risks associated with GDMOs are currently unclear. NIH must develop a systematic decision tree or risk assessment matrix for GDMOs, which would include information on how to model potential off-target effects and persistence in the environment. This will allow IBCs to consistently make assessments of these uncertain projects.

307. Debbie Eckert

I am responding: On behalf of myself

Name: Debbie Eckert

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: It would be helpful to have an expanded explanation of the intended scope of the policy, including examples of research within scope and outside of scope. As written, the scope is not entirely clear.

The beginning of the explanation of the scope of the policy indicates it "covers all biomedical research, in laboratory settings, involving biohazards." Is research using a tool described later in the scope (e.g., a genetically modified organism), in the lab, but with non-biomedical focus and non-NIH funding (e.g., environmental studies funded by NSF) considered outside of scope? One such example could be the study of the microbiome of a mammal, including genetic manipulation of said microbiome, to determine the impact on metabolism and survival in climate extremes.

The remaining definition of the scope in the policy is: "research involving … known or potential risk to human health and any of the following:
1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above."

Does the scope of covered research have to have a known or potential risk to humans AND be included on the list below? What if it is only one or the other? Or does the scope imply that anything on the numbered list could have a potential risk to humans? i.e., Is there flexibility for institutions to perform risk assessments to determine what requires IBC review? e.g., If the institution decides a genetically modified organism housed at ABSL1 is not a potential risk to human health, can their IBC decide it is outside of the scope of the policy and decline to review it?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): One of the primary objectives stated throughout the modernization effort was to expand oversight of higher-risk activities while simultaneously reducing unnecessary burden for low-risk research. Indeed, the introduction in the draft indicates the removal of "red tape for low-risk research." The draft successfully broadens oversight

to include many biological hazards beyond recombinant and synthetic nucleic acid technologies; however, it is less clear how the proposal reduces burden for lower-risk activities.

RG1 wild-type agents are excluded, but RG1 derivatives and other low-risk materials are included. These include:
• genetically modified RG1 agents, with an expansive definition for genetic modification;
• transgenic organisms at BSL-1/ABSL-1;
• plasmids with low-risk inserts;
• replication-incompetent, non-integrating viral vectors;
• well-characterized cell lines; and
• non-Select Agent toxins.

While the ability to use delegated review is a welcome addition, requiring it for low-risk activities will likely increase review and documentation requirements (for researchers as well as IBC delegates).

A gap analysis at our institution indicates we will have to invest substantial effort into identifying low-risk research that is not currently covered under the NIH guidelines but will be covered under the new policy. I do not believe this is the intent of the new policy, and request that research that can be safely conducted at BSL1 containment be exempt from the policy entirely. This will allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval. When the dominant interaction between biosafety professionals and researchers involves cataloguing low-risk biological agents, administrative fatigue decreases cooperation and buy-in for the more impactful, higher-risk research.

Along the same lines, the proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public posting of all incident reports using the required template including PI names and funding details could expose personal information, lead to security concerns, and substantially damage a strong reporting culture. At our institution, it could reverse our years' long effort to improve laboratory safety culture, including near-miss reporting. Some research areas are prone to security concerns for researchers, where identification, even generally, could put their personal safety at risk. In many small laboratories, the details contained in the required template could easily lead to identifying specific individuals involved in the incident, violating privacy concerns and in some cases HIPAA protected information.

The effort to gather incident data and provide actionable transparency in laboratory safety practice is noteworthy. I suggest these goals could be achieved with anonymized, aggregated public reporting.

6. Other feedback relevant to this resource: As the approval of an institutional Biosafety Assurance is an entirely new step in IBC operation, please provide additional implementation guidance regarding the process, including examples and/or suggested templates, the expected timeline, and the criteria for approval.

The proposed six-month effective date for implementation will place an unrealistic burden on research institutions and set them up for non-compliance from day one. The research community is supportive of oversight modernization and wants to be a partner in the process. Please allow us the time that will be required to realistically reach compliance with an entirely new oversight paradigm. Some of the tasks that will be required for complying include: inventorying newly covered research, obtaining an approved Biosafety Assurance, revising written institutional policies, redesigning electronic systems, and training researchers, administrators and the IBC. Please provide at least 24 months after publication of the final policy and complete implementation materials.

Uploaded File: DME-final-comments-on-NIH-Draft-Biosafety-Policy.docx

Thank you for the substantial effort dedicated to modernizing biosafety oversight and for the opportunity to provide comments on the published Draft NIH Biosafety Policy for Research Involving Biohazards. Although I am the Biosafety Officer at the University of Utah, these comments represent my personal opinion, and they should not be interpreted to be representative of the views of the University of Utah. I applaud the meaningful progress in proposed oversight which is demonstrated by the expansion beyond recombinant and synthetic nucleic acid research to wild type human pathogens and biological toxins, as well as the addition of a delegated IBC review tier.

At the same time, the proposed policy would substantially expand review, documentation, public-posting, assurance, and reporting obligations. The result will be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions, which is contrary to the stated objective of "removing red tape for low-risk research."

Below I provide constructive criticism that I hope will be considered for the next draft of the new policy. Additionally, due to the request for substantial changes in the final requirements, I request you will **provide an opportunity for public review and comment on the next draft before it is finalized.**

Topic: SCOPE

It would be helpful to have an expanded explanation of the intended scope of the policy, including examples of research within scope and outside of scope. As written, the scope is not entirely clear.

The beginning of the explanation of the scope of the policy indicates it "covers all biomedical research, in laboratory settings, involving biohazards." Is research using a tool described later in the scope (e.g., a genetically modified organism), in the lab, but with non-biomedical focus and non-NIH funding (e.g., environmental studies funded by NSF) considered outside of scope? One such example could be the study of the microbiome of a mammal, including genetic manipulation of said microbiome, to determine the impact on metabolism and survival in climate extremes.

The remaining definition of the scope in the policy is: "research involving … known or potential risk to human health and any of the following:

1. Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above."

Does the scope of covered research have to have a known or potential risk to humans AND be included on the list below? What if it is only one or the other? Or does the scope imply that anything on the numbered list could have a potential risk to humans? i.e., Is there flexibility for institutions to perform risk assessments to determine what requires IBC review? e.g., If the institution decides a genetically modified organism housed at ABSL1 is not a potential risk to human health, can their IBC decide it is outside of the scope of the policy and decline to review it?

Topic: STREAMLINING OF ADMINISTRATIVE BURDEN

One of the primary objectives stated throughout the modernization effort was to expand oversight of higher-risk activities while simultaneously reducing unnecessary burden for low-risk research. Indeed, the introduction in the draft indicates the removal of "red tape for low-risk research." The draft successfully broadens oversight to include many biological hazards beyond recombinant and synthetic nucleic acid technologies; however, it is less clear how the proposal reduces burden for lower-risk activities.

RG1 wild-type agents are excluded, but RG1 derivatives and other low-risk materials are included. These include:
• genetically modified RG1 agents, with an expansive definition for genetic modification;
• transgenic organisms at BSL-1/ABSL-1;
• plasmids with low-risk inserts;
• replication-incompetent, non-integrating viral vectors;
• well-characterized cell lines; and
• non-Select Agent toxins.

While the ability to use delegated review is a welcome addition, requiring it for low-risk activities will likely increase review and documentation requirements (for researchers as well as IBC delegates).

A gap analysis at our institution indicates we will have to invest substantial effort into identifying low-risk research that is not currently covered under the NIH guidelines but will be covered under the new policy. I do not believe this is the intent of the new policy, and **request that research that can be safely conducted at BSL1 containment be exempt from the policy entirely**. This will allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval. When the dominant interaction between biosafety professionals and researchers involves cataloguing low-risk biological agents, administrative fatigue decreases cooperation and buy-in for the more impactful, higher-risk research.

Along the same lines, the proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and **assign oversight based on the resulting phenotype and risk.**

Topic: SCOPE OF PUBLIC INCIDENT REPORTING

Public posting of all incident reports using the required template including PI names and funding details could expose personal information, lead to security concerns, and substantially damage a strong reporting culture. At our institution, it could reverse our years' long effort to improve laboratory safety culture, including near-miss reporting. Some research areas are prone to security concerns for researchers, where identification, even generally, could put their personal safety at risk. In many small laboratories, the details contained in the required template could easily lead to identifying specific individuals involved in the incident, violating privacy concerns and in some cases HIPAA protected information.

The effort to gather incident data and provide actionable transparency in laboratory safety practice is noteworthy. I suggest these goals could be achieved with anonymized, aggregated public reporting.

Topic: IMPLEMENTATION TIMELINE

The proposed six-month effective date for implementation will place an unrealistic burden on research institutions and set them up for non-compliance from day one. The research community is supportive of oversight modernization and wants to be a partner in the process. **Please allow us the time that will be required to realistically reach compliance with an entirely new oversight paradigm.** Some of the tasks that will be required for complying include: inventorying newly covered research, obtaining an approved Biosafety Assurance, revising written institutional policies, redesigning electronic systems, and training researchers, administrators and the IBC. Please provide at least 24 months after publication of the final policy and complete implementation materials.

Topic: IMPLEMENTATION GUIDANCE

As the approval of an institutional Biosafety Assurance is an entirely new step in IBC operation, please provide additional implementation guidance regarding the process, including examples and/or suggested templates, the expected timeline, and the criteria for approval.

Thank you again for your continued leadership in advancing and modernizing biosafety oversight. I appreciate NIH's engagement with the biosafety community and hope we can work together to ensure that the final policy is clear, allows the allocation of resources based on risk, and is effective in supporting both scientific progress and the safety of researchers and

308. Dana-Farber Cancer Institute

I am responding: On behalf of an organization

Name: Caroline Powers

Name of Organization: Dana-Farber Cancer Institute

Type of Organization: Healthcare Institution

Role: Healthcare Provider

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Oncology/cancer research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-RFI-Biosafety-Policy-for-Research-v3-10.14.26.pdf

Description: Dana-Farber Cancer Institute supports the draft NIH biosafety policy overall but urges revisions to public incident-report posting requirements to protect disclosure, reduce reputational harm, and exempt certain lower-risk incidents, while endorsing confidential near-miss reporting through NBDSAC.

DFCI Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards, Notice Number NOT-OD-26-112

Dear NIH Office of Science Policy:

Dana-Farber Cancer Institute (Dana-Farber) appreciates the opportunity to comment on the draft policy, *NIH Biosafety Policy for Research Involving Biohazards*. Dana-Farber is an NCI-designated comprehensive cancer center and a teaching affiliate of Harvard Medical School. Our mission is to deliver expert and compassionate care while advancing the science of cancer—improving understanding, diagnosis, treatment, cure, and prevention of cancer and related diseases. We are proud to be a global leader in cancer research, diagnostics, and clinical care. Dana-Farber is also a proud and longstanding partner of the federal government in U.S. scientific innovation and biomedical advancement. As you know, like other research institutions across the country, research conducted at or sponsored by Dana-Farber is subject to federal, state, local, and institutional biosafety requirements. The Dana-Farber Institutional Biosafety Committee (IBC) provides centralized biosafety review and oversight for biological research conducted at or sponsored by the institution.

Dana-Farber supports the draft policy, *NIH Biosafety Policy for Research Involving Biohazards*, which would strengthen institutional biosafety programs. The draft policy is consistent with the current policies and procedures of Dana-Farber's IBC, and its Environmental Health & Safety Office of Biosafety, which identifies biological safety practices, procedures, facility construction, and operational standards for the safe handling and use of biohazardous materials. Dana-Farber leadership supports the Office of Biosafety in its implementation of a risk-based and evidence-based approach to oversight of basic and clinical research involving biological materials.

We respectfully request that the NIH Office of Science Policy consider the following comments in its revision of the draft policy.

With regard to public posting of IBC minutes, Dana-Farber's IBC already publicly posts minutes of its convened committee meetings and Dana-Farber expects to be able to comply with the draft minutes template. However, Dana-Farber is concerned about the public posting of incident reports as this practice may discourage the institutional workforce from disclosing actual incidents, accidents, and near misses. Furthermore, the public posting of incident reports may create reputational harm for the Principal Investigator (PI). Dana-Farber therefore recommends revision of the incident report template to exclude the name of the PI, or alternatively, NIH allow redaction of this information. Dana-Farber further recommends exempting lower-risk incidents involving

BSL-1/ABSL-1 or certain BSL-2/ABSL-2 work from the requirement for public posting. The IBC must review certain lower-risk incidents described below:

1. Any incident involving research subject to the policy with an animal that is housed at BSL-1/ABSL-1 or BSL-2/ABSL-2 (e.g., bite, scratch, escape or improper disposition); or
2. Any incident at BSL-1/ABSL-1 or BSL-2/ABSL-2 that does not involve agent-specific medical treatment when first aid is administered.

Such lower-risk incidents do not require reporting to the NIH and are instead evaluated by the Environmental Health & Safety Office of Biosafety. These incidents are presented to the IBC for discussion and documented in the publicly posted minutes of the IBC meetings, so there is limited benefit of publicly posting separate reports of these lower-risk incidents, particularly given the potential to discourage the institutional workforce from disclosing actual incidents, accidents, and near misses, as well as the potential for reputational harm. Additionally, it should be clarified that minor spills of low-risk agents, that do not involve a breach of containment and that were properly cleaned and decontaminated, generally are not subject to the incident report requirements, including public posting.

Dana-Farber supports the draft policy's recommendations that institutions "submit voluntary, confidential reports regarding near-misses, secondary failures, or procedural issues to the National Biosafety Data and Safety Analysis Center (NBDSAC)." The proposed NBDSAC provides a more appropriate framework for public transparency and for analysis by biosafety practitioners in a non-punitive manner. The capability of the NBDSAC to aggregate and de-identify data will support subsequent analysis to identify recurring hazards, contributing factors, corrective actions, and national trends while minimizing potential harm to individual workforce members, principal investigators, or institutions that could result from incident-specific public reporting.

309. Peter K. Rogan

I am responding: On behalf of myself

Name: Peter K. Rogan

Name of Organization: Cytognomix

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Organizational Official

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Genomics bioinformatics

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy incorrectly states that altering the expression of genes for example mRNA therapies is covered by genetic modification. Altering gene expression is transient, unlike gene modification which is effectively permanent. Furthermore, many compounds or other environmental stimuli can alter gene expression without altering a genome.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): None

3. Continued utility of Risk Groups: Not applicable

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Don't redefine this policy in such a way that it is no longer scientifically compliant.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: None

6. Other feedback relevant to this resource: None

310. John McCarthy

I am responding: On behalf of myself

Name: John McCarthy

Name of Organization: Countermeasures Research

Type of Organization: Other

Type of Organization - Other: Analysis and Research

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Medical countermeasures (antifungal and antiviral drug development); biosecurity.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: This comment supports basing the scope on biohazards rather than genetic modification and also recommends recognizing overlap with existing federal oversight and addressing an oversight gap.

The Policy should recognize that clinical specimens are already under federal oversight. A CLIA-certified diagnostic laboratory conducting research on patient blood under an IRB-approved protocol operates under the OSHA bloodborne pathogens standard and under the facility and safety requirements of its CLIA certification, and its practices and records are subject to inspection. Section IV-2 of the Policy nonetheless requires IBC review before initiating “Research with primary cells that may be contaminated by adventitious agents,” and patient blood can meet that description. The draft’s other-agency provision already allows such research to “proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained.” The Policy should name the OSHA bloodborne pathogens standard, as applied in a CLIA-certified laboratory, as oversight that qualifies, so that an IRB-approved study that handles and tests patient blood in a CLIA-certified laboratory under universal precautions is not also subject to an IBC review that duplicates any protections those programs already require. Culturing or propagating patient cells would remain under Section IV-2.

Proposed text, as an addition to the other-agency provision in Section II: "Research in which human clinical specimens are handled and tested in a CLIA-certified laboratory under the OSHA bloodborne pathogens standard, 29 CFR 1910.1030, is research under the purview of another federal agency for purposes of this provision. Culture or propagation of such specimens remains subject to Section IV-2."

The Policy should also address an oversight gap regarding genetically modified plants. The draft excludes them from the definition of biohazard, “Cells, viruses, or organisms, other than plants, that have been genetically modified,” and from Section IV-2. Appendix P of the current NIH Guidelines sets containment requirements for that work. The new Policy is expected to supersede the Guidelines and retain content

from Appendices B and G-II-C-5, but it does not currently address Appendix P. USDA review under 7 CFR part 340 covers the import, interstate movement, and environmental release of regulated plants, not contained laboratory work. The draft already directs IBCs to weigh harm to “the environment.” Rather than suggesting that the NIH adopt agricultural oversight, this comment suggests clarifying what will replace Appendix P for contained work with genetically modified plants at NIH-funded institutions.

Proposed text: "Contained laboratory and greenhouse research with genetically modified plants at institutions under this Policy will adhere to the containment practices of Appendix P of the NIH Guidelines, maintained as an implementation resource."

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): This comment supports the proposed three-tier (federal, institutional, and investigator) system calibrated to research risk and suggests further consideration of accountability and the administrative burden on small awardees.

The Policy does not define "institution." Its General Definitions cover Biosafety Assurance, the IBC, laboratory research, and NIH-supported research, but not the entity that bears the obligations. The obligations state that institutions must "establish an IBC" of "at least five members," include "at least two members who are not affiliated with the institution"; train principal investigators and "laboratory staff"; post minutes and incident reports "on a public-facing webpage on the website of the institution"; and have their biosafety officer or designated official conduct "periodic inspections to ensure that laboratory biocontainment facilities and equipment are functioning properly." These obligations describe an institution that operates its own laboratory facility, such as a university, a medical center, or an established company. However, early-stage start-up biotechnology companies often do not. They have a few employees, rent bench space in a shared laboratory run by an incubator, and outsource work to universities and contract research organizations.

Recommendation: Define "institution" and distinguish the awardee from the institution conducting the research.
Proposed text for the definition: "Institution: the legal entity that operates the facility in which research subject to this Policy is conducted, or that sponsors such research."

The obligations, as written, are disproportionate for small start-ups with few employees and a limited budget, and run counter to the draft’s own criterion of “streamlining of administrative burden.” Under the draft, “no research within the scope of this Policy is conducted until approved by the IBC, or IBC delegate,” so whatever its risk level, the work is reviewed where it is done; a second committee at the awardee would add burden and duplicate that review. The draft as written also applies to small start-ups as “an institution that receives any NIH funding,” which can be interpreted in two different ways. Under one interpretation, the Assurance comes from “the institution conducting the research,” which places it with the university or contract laboratory where the work is done. Under the other, the awardee is itself an institution that must “establish an IBC” and ensure that research “conducted at or sponsored by the institution, irrespective of the source of funding” complies. The draft does not clarify or choose between the two, and its templates set rules for an externally administered IBC that the Policy mentions once and does not define. Under the second interpretation, a start-up with one SBIR or STTR Phase I award must hold its own Assurance and a five-member IBC for every project, including privately funded ones. A five-

member committee with two unaffiliated members can be larger than the small start-up and would require it to meet the external committee requirement, with resources from a Phase I budget. That payment would buy a second review of work that the IBC of the institution where it is performed would approve. The split is not the start-up's choice: under an STTR award, the statute requires at least 30 percent of the work be performed at the research institution, so the split between the awardee and the laboratory is a matter of program design.

Recommendation: Every institution should still file its own Assurance so NIH maintains a signed commitment from each awardee it funds. However, awardees whose research is conducted at an institution holding an NIH-approved Assurance should be allowed to meet their obligations through that institution. The awardee's Assurance would document a written reliance agreement under which the performing institution's IBC and biosafety program review and oversee the work, and the agreement would assign incident reporting and posting to the institution where the work is performed. This mirrors IRB policy for human subjects research: institutions keep their own Assurance, with a single review board. When a start-up rents bench space in a shared laboratory run by an incubator, the Policy should clarify responsibility for the Assurance, the IBC, and any reliance agreement.

Proposed text for reliance: "An institution that sponsors research performed at another institution holding an NIH-approved Biosafety Assurance may satisfy Section III-A for that research by documenting, in its own Assurance, reliance on the performing institution's IBC and biosafety program under a written reliance agreement."

Three further recommendations. First, set a period within which NIH will act on a new Assurance: Phase I awards run up to twelve months, and the current draft does not address this. Second, companies can hold multiple awards; an NIH STTR alongside Department of Defense or BARDA awards, and Department of Defense award terms already require adherence to the NIH Guidelines. The draft can indicate whether such terms fall under the "regulation or purview of another federal agency," and NIH can work with those agencies so their terms reference this Policy from the same effective date; otherwise, a laboratory can be held to multiple guidelines by different funders. Third, contract research organizations and incubator laboratories may not have NIH funding and therefore not hold an Assurance for an awardee to rely on. NIH could offer voluntary Assurances to institutions performing research for NIH-funded sponsors without receiving NIH funding themselves.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

311. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: If the intent of the policy is to expand oversight for meaningful biosafety risks while avoiding unnecessary administrative burden for routine, low-risk work, the draft should be revised to better align its requirements with that objective. As currently written, the policy could substantially expand institutional review, documentation, reporting, and public-posting obligations for materials and activities that may present minimal biosafety risk. NIH should establish appropriate exemptions, administrative registration pathways, or other mechanisms for clearly defined low-risk activities.

Several important terms appear to be undefined or insufficiently precise. Clear and internally consistent definitions are needed for terms such as “biohazard,” “biological agent,” “genetic modification,” “biomedical research,” “toxin,” and “genetically modified organism.” Clear definitions are essential to ensure consistent institutional determinations and risk-based application of the policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Comment.pdf

Subject: Support for CSHEMA Recommendations on the Draft NIH Biosafety Policy

To Whom It May Concern:

I am submitting this comment in response to NIH's request for public comment on the Draft NIH Biosafety Policy for Research Involving Biohazards, issued under NOT-OD-26-112.

I support the comment submitted by the **Campus Safety, Health, and Environmental Management Association (CSHEMA)** regarding this effort. CSHEMA's comment appropriately reflects the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

As an environmental health and safety professional working in higher education, I support CSHEMA's recommendations and would like to amplify the following key points that I believe warrant particular attention:

- **Definitions:** Several important terms appear to be undefined or insufficiently precise. Clear and internally consistent definitions are needed for terms such as "biohazard," "biological agent," "genetic modification," "biomedical research," "toxin," and "genetically modified organism." Clear definitions are essential to ensure consistent institutional determinations and risk-based application of the policy.
- **Scope and risk calibration:** If the intent of the policy is to expand oversight for meaningful biosafety risks while avoiding unnecessary administrative burden for routine, low-risk work, the draft should be revised to better align its requirements with that objective. As currently written, the policy could substantially expand institutional review, documentation, reporting, and public-posting obligations for materials and activities that may present minimal biosafety risk. NIH should establish appropriate exemptions, administrative registration pathways, or other mechanisms for clearly defined low-risk activities.
- **Protect Personal Information:** As written, the incident report template raises privacy concerns for exposed individuals and would likely discourage reporting. Please allow public reporting that does not include information on the lab or role of the individual involved.
- **Second review opportunity:** Given the potential extent of revisions needed to address the concerns raised by CSHEMA and others, NIH should provide a second public review and comment period after substantial revisions are made and before the policy is finalized. A second review would allow stakeholders to evaluate how the revised definitions, scope, oversight categories, reporting requirements, and implementation provisions operate together.
- **Implementation timeline:** The proposed six-month implementation period is not sufficient for institutions to assess newly covered research, revise policies and procedures, update review and reporting systems, train affected personnel, obtain institutional approvals, and secure necessary resources. I support CSHEMA's recommendation for a minimum 24-month phased implementation period and believe that, given the breadth of the proposed changes, a three-year implementation period would be more realistic.

I also encourage NIH to engage representatives from CSHEMA or ABSA International while updating the draft policy to provide real-time feedback on changes that are being made.

Thank you for the opportunity to comment.

312. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Other

Type of Organization - Other: Biosafety Professional

Role: Organizational Official

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Expansion of the scope is helpful in addressing biohazards more broadly but the policy is inconsistent about the applicability of human, animal, and plant health impacting organisms and oversight. The definition of biohazards is not well defined. Many definitions in the document are lacking, unclear, or incorrect/incomplete.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Requiring an incident reporting template and meeting minutes template do not allow for flexibility in how organizations may collect and investigate these situations. Inclusion of personally identifiable information in the incident reporting template (like PI name and position title of involved individuals) and the requirement for it to be publicly available (not just submitted to NIH) will lead to underreporting of incidents which can negatively impact safety. Research security is also a concern for publicly reporting so much information about activities and their locations. Aggregated information should be compiled and reported as such, more akin to the way that the Public Health Agency of Canada (PHAC) does their incident reporting.

6. Other feedback relevant to this resource: 6 months for implementation is categorically insufficient especially for large organizations with large research programs especially those that have not been fully

covered by this expanded policy scope. Any required documentation/submissions should have templates as a starting point that are allowed to be modified so long as they contain the required information.

Uploaded File: NIH-comments.pdf

Firstly, I would like to thank the NIH for the opportunity to submit comments on the Draft NIH Biosafety Policy for Research Involving Biohazards. This policy has broad impact across organizations that handle biological materials and receive NIH funding, and the involvement of the regulated community is a welcome addition to the policymaking process.

This document is a good first draft policy however many changes are needed to make it acceptable to the regulated community and therefore I would suggest another draft after revisions and round of public comments would be appropriate.

I fully support the comments submitted by both CSHEMA on October 12th, 2026, and ABSA International dated October 19th, 2026, and am therefore incorporating them in their entirety by reference into my response.

The expanded scope is appreciated as it provides more coverage of biological hazards that are worked with in laboratory settings. However, not requiring that organizations have Biosafety Officers with institutional responsibilities and authority is short-sighted and impacts the ability of the IBC to evaluate risk associated with biohazards. This is also an unfunded mandate that requires a large administrative burden on the EHS/HSE office and the BSO and does not unfortunately elevate the IBC to level of institutional importance of an IACUC or IRB committee. Biosafety and biocontainment are critically important in organizations and needs to be treated as such by requiring trained and competent professionals be included in all biohazard risk assessments and regulatory oversight.

Requiring an incident reporting template and meeting minutes template do not allow for flexibility in how organizations may collect and investigate these situations. Inclusion of personally identifiable information in the incident reporting template (like PI name and position title of involved individuals) and the requirement for it to be publicly available (not just submitted to NIH) will lead to underreporting of incidents which can negatively impact safety. Research security is also a concern for publicly reporting so much information about activities and their locations. Aggregated information should be compiled and reported as such, more akin to the way that the Public Health Agency of Canada (PHAC) does their incident reporting.

Allowing for only 6 months for implementation is categorically insufficient especially for large organizations with large research programs especially those that have not been fully covered by this expanded policy scope.

Thank you again for this opportunity and I hope that we are able to see another draft before finalization of this critically important, wide-reaching biosafety policy.

313. Scott B. Snapper, MD PHD

I am responding: On behalf of myself

Name: Scott B. Snapper, MD PHD

Name of Organization: Boston Children's Hospital

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Immunology and Inflammatory Bowel Diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definition of Genetic modification includes nucleic acid molecules that "can be transcribed or translated." Read together with Section II.2, which brings "cells, viruses, or organisms, other than plants, that have been genetically modified" into scope, this classifies any cell transfected with synthetic mRNA, siRNA, or a transient expression plasmid as a biohazard.

This is scientifically inaccurate, and I believe it is unintended. Three of the four criteria depend on stability or replication—including the fourth, which expressly requires "stable alterations into the genome." The third has no such limiter. Transfected mRNA alters no genome: it does not enter the nucleus, is not replicated, is not heritable, and is degraded within days. What changes is the proteome, transiently. As written, the criterion would equally capture any agent that alters transcription.

The practical consequence is substantial. The draft includes no equivalent to Section III-F-1 of the current NIH Guidelines, which exempts synthetic nucleic acids that can neither replicate nor integrate and do not encode a potent toxin. Section IV-3 instead routes to delegated review work that is exempt today, including "plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes" and "well-characterized cell lines." For a research division of moderate size this converts a large volume of routine, genuinely low-risk work into registered protocols — contrary to the policy's stated aim of removing red tape for low-risk research.

Recommendation. Amend the third criterion to read: "Can be transcribed or translated to yield a toxin, virulence factor, or select agent product, or a product meeting the criteria above." Alternatively, add an exempt category below Section IV-3 for non-replicating, non-integrating nucleic acids that do not encode such products. Either approach preserves NIH's coverage of hazardous encoded products without asserting that a transiently transfected cell has been genetically modified.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

314. RAIF GEHA

I am responding: On behalf of myself

Name: RAIF GEHA

Name of Organization: BOSTON CHILDRENS HOSPITAL

Type of Organization: Healthcare Institution

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): ALLERGY

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy proposed includes Transient expression of nucleic acids that “can be transcribed or translated” as a genetic modification. This is not the case by definition. Thus thi Transient expression of nucleic acids y should not be included

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

315. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The new addition that genetic modification also relates to being "transcribed or translated" while the genome is not altered is too broad in my view. In most cases this does not alter the cells (genome) permanently and I think this would lead to an overregulation with severe consequences for research and technology that is highly beneficial to humans e.g. for their health. I could follow a logic that being "transcribed or translated" needs to be considered more, if the product yields a modification on the genome that can be inherited and replicated upon division. However, such path to such genetic modification would already be captured with the other categories.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

316. Phillip D. Zamore

I am responding: On behalf of myself

Name: Phillip D. Zamore

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Currently, definitions of genetic modification require a permanent change to the genetic material of the host cell or organism, for example modification of their genomic DNA (or genomic RNA for select viruses). The new policy language would reclassify any nucleic acid that “Can be transcribed or translated”, including most transiently introduced transfected plasmids, exogenous mRNAs, and several vaccine technologies as a "genetic modification". This re-classification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research and in recombinant vaccine technologies, with potentially devastating public health outcomes.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): This is fine

3. Continued utility of Risk Groups: If it isn’t broken, don’t fix it!

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Waste of time.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

317. Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

I am responding: On behalf of myself

Name: Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 4-Biosafety-Policy-Comments-to-NIH-OSP.docx

Description: high-level comments regarding Policy Draft

Priority requests to NIH OSP Regarding Biosafety Policy Draft

- **<u>Define the minimum requirements for an Instutional Biosafety Program.</u>**

  1. Partial quote: '*. . . the National Institutes of Health (NIH) is committed to ensuring that* ***gold-standard science*** *is conducted under* ***gold-standard biosafety conditions****.*"
  A single, egregious oversite is that the requirement for a "Biosafety Officer" defaults to that listed in the current NIH Guidelines. How can an institution empower and run a "**gold-standard biosafety program"** without mandating a program lead that has significant biosafety experience?

  2. Pick a consistent title for the policy that reflects what the NIH wants / needs: Is this a "Biosafety Policy", a "Biosafety & Biosecurity Policy", or a "Policy for work with Biohazards"? Each of the titles will be interpreted differently by institutional leadership.
  This is important because the draft title "***Biosafety Policy for Research Involving Biohazards"*** (Biosafety & Biosecurity Policy?) does not address the fact that biosafety programs include a comprehensive administrative portfolio that includes research safety, compliance, ethics, training, committee review, and approval portfolio.

  3. Define what level of institutional empowerment must be granted to the Biosafety & Biosecurity program. Must both components be supported or is either one, biosafety or biosecurity, adequate to satisfy this policy?
  A biosafety officer or biosafety professional overseeing this gold standard biosafety program must be granted administrative level empowerment equivalent to the "Director of Animal Welfare", Director of Human Research Protections" or the "Institutional Veterinarian". A more appropriate role, to accomplish what the NIH is striving toward, will be Assistant or Associate Vice Provost or Vice President for Biosafety & Biosecurity Programs. Someone at the institutional leadership level, with appropriate biosafety experience, must be empowered to oversee these programs. **This must be mandated by the policy or it won't happen.** Lack of this empowerment is currently what fails many biosafety programs.

- **<u>Codify the Institutional Biosafety Committee (IBC)</u>**

  1. Define what level of institutional support is adequate to satisfy policy requirements. Must Institutional resources include similar administrative structure for the IBC that is offered to the IRB and/or IACUC? What is the minimum? Office

space, administrative support adequate for the number of IBC committees (or sub-committees), Leadership team consisting of Director, Associate Director, Professional staff separate from the biosafety program? For example, the Director of the IBC office has a separate role from Institutional Biosafety Officer, etc.? The Biosafety Officer sits as a voting member only?

- **Fully Embrace Risk-Based Biosafety**

  1. It is stated that this policy intends to encourage and embrace risk-based oversight and reporting. Yet, the only risk criteria incorporated into this first draft are Biological Agent Risk Groups and Biosafety Levels. These criteria are not applicable to all life science research activities or agents proposed for enhanced biosafety oversight. For example, biologics used in clinical trials cannot be defined by a biological agent Risk Group. Biologics are typically risk assessed by Risk Banding. Include/acknowledge this aspect of risk assessment in the updated draft. Alternatively, allow the biosafety professionals overseeing biosafety programs the freedom to perform risk assessment without specifying the risk criteria that must be used, because in biosafety and especially because of rapidly developing life sciences research programs, "it depends". Please let life science research professionals do what they do best, without restriction.

318. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 3-NIH-Biosafety-Policy-Comments.docx

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public confidence in NIH-supported science. I offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

Topic to Address*: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any

resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.

3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory

rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:
    a. the nature and stability of the genomic modification;
    b. whether the modification is heritable and the potential for transmission through breeding;
    c. effects on animal health, phenotype, host range, susceptibility, or disease;
    d. potential entry into breeding or food-production systems;
    e. potential environmental release or interaction with non-research animal populations;
    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and
    g. applicable federal, state, or other regulatory oversight.
2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.
3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.
4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

  deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the

Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

b. State explicitly that the Policy does not address non-biological hazards.

c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

  Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

  the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate, and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

  Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and

Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

I believe the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, I request that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, I welcome the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. I do not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. I recommend that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice

- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, I recommend a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with my earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*
- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. I recommend that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior

leadership;

2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply

another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.
NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, I kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. I encourage NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE

BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The

Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While I support appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes
6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions

throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as “any incident,” “loss of containment,” “significant problems,” and “minor spills... generally do not need to be reported,” and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report “potential releases involving facility and/or equipment failures even when redundant systems were functioning properly” would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure

in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: I recommend the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and

occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. I support preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

319. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 2-Feedback-NIH-Comments.docx

Comment to NOT-OD-26-112

I appreciate NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions.

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk

and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under

the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure,"

“compliance violation,” and “minor spill.” The policy should clarify whether precautionary post exposure prophylactic treatment is considered “agent-specific treatment”. It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

5. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures,

workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

Recommend that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

320. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 1-Recommendations-to-the-NIH-OSP.docx

I ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

1. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts;

compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

2. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure

implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological

exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

3. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

4. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

5. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

6. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and

explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

7. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions.

Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

321. Anonymous

I am responding: On behalf of myself

Name: Anonymous

Name of Organization: NA

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: NIH's goal of modernizing biosafety oversight and expanding oversight beyond recombinant and synthetic nucleic acid research is commendable. However, the proposed scope is broader than necessary and would likely capture substantial amounts of routine, low-risk research without a clear idea of additional biosafety benefit. The definition of biohazards and the categories of research subject for oversight must be defined appropriately to help differentiate work scope, which is true biosafety risk from activities that are well characterized, routine, or adequately addressed through existing institutional controls.

The current scope will most likely and inadvertently create several administrative challenges:
• Expansion of IBC review to routine low-risk activities will divert or dilute institutional resources (these are finite resources) away from higher-risk research requiring greater biosafety scrutiny.
• The draft policy does not clearly distinguish research from diagnostic testing, assay development, quality assurance activities, method validation, or other operational laboratory functions, creating uncertainty regarding applicability.
• The policy applies broadly to all NIH-funded institutions, directly or indirectly through sub-contracts or other contract mechanisms. There will be high variability in interpretation and implementation across institutions.

Recommendation: NIH should establish clearer exclusion, exemption, notification, and/or registration categories for well-characterized, minimal-risk activities and provide examples illustrating what research falls within and outside the scope of the policy. This would improve consistency while preserving oversight of genuinely higher-risk research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered oversight framework is appropriate and necessary. The concept that oversight requirements should be proportional to risk and uncertainty is appreciated. However, the proposed framework does not adequately distinguish between high-risk, moderate-risk, and routine low-risk activities. Although the draft includes delegated review pathways for certain lower-risk activities, significant administrative requirements are tied with protocol review, documentation, approval tracking, renewals, reporting,

public posting, and record retention. As a result of this draft policy, delegated review will affect committee discussion time without substantially reducing overall institutional burden.

Recommendation:
Reserve full IBC review for research involving novel hazards, significant uncertainty, elevated containment requirements, or substantial modifications to biological agents with true risks (e.g. use of synthetic biology to create an organism to increase biofuel production include a gain of function but this activity does not fall under high risk research).
• Introduce and expand exemption with examples, registration-only, and/or notification pathways for low-risk activities.
• Allow abbreviated continuation reviews for stable, previously approved protocols (i.e. umbrella projects). E.g. allow reliance on existing federal oversight mechanisms where equivalent reviews have already occurred.

Without additional calibration to perceived risks, the proposed draft policy will shift biosafety resources toward administrative processing of routine work while reducing institutional capacity to focus on emerging technologies, high-containment research, and incident prevention.

3. Continued utility of Risk Groups: Risk Groups (RG) provide a very useful and widely understood baseline framework for biological-agent hazard identification. However, Risk Groups alone are insufficient for evaluating the full spectrum of risks associated with modern biotechnology and should not be used as the sole determinant of oversight requirements. Risk assessments should continue to incorporate: Agent pathogenicity, Genetic modifications, Route of exposure, Experimental design, Host range, Scale and concentration, Environmental considerations, Available countermeasures, Containment and operational practices.

Recommendations:
Maintain RGs as an initial reference point and emphasize comprehensive project-specific risk assessment.
NIH should provide additional guidance on how RGs interact with Biosafety Levels, genetically modified agents, synthetic biology platforms, gene-drive technologies, and emerging technologies that do not fit neatly into traditional agent-based classifications. This is critical given the increased interest in synthetic biology and use of AI into research designs.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH's goal of fostering broader adoption of biosafety best practices beyond institutions formally subject to the policy is appreciated. However, voluntary compliance is unlikely to increase if the final policy is perceived as excessively burdensome, highly prescriptive, or punitive (which frankly is how it is read and perceived). The following aspects/requirements will definitely discourage participation:
1. Extensive public disclosure requirements.
2. Significant documentation and reporting obligations.
3. Administrative costs associated with implementation (NOTE: all institutions have finite funding, receive limited indirect costs with their grants, and thus EHS has limited staff, who are already overworked).

4. Potential reputational consequences arising from public incident reporting (Practical scenario – no graduate student or postdoctoral fellow or PI will willingly come forward for any type of incident reporting if they knew that NIH plans to post or rather splatter their names on public website. This can be perceived as a public shaming exercise in the name of transparency.

NIH must make sure that institutions adopting this approach voluntarily are not expected to implement the full administrative infrastructure required of large NIH-funded research organizations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: NIH's effort to improve lesson-sharing and incident-learning across the research enterprise is very commendable. However, the current public reporting and transparency provisions create substantial concerns related to security, confidentiality, intellectual property, and reporting culture.
The draft requires public posting of:
• IBC meeting minutes.
• Incident reports.
• IBC rosters.
• Training summaries.
• Related biosafety program information.

While transparency is important, broad public disclosure creates risks including but not limited to National Security and Biosecurity Risks. Publicly available incident reports, meeting discussions, facility information, and governance documentation will lead to aggregation of information about:
• High-containment capabilities.
• Research focus areas.
• Operational vulnerabilities.
• Security controls.
• Incident response procedures.
Do you see countries like China, Iran, North Korea, and Russia provide this level of granularity of information openly? These countries are using our/United States'publicly available information against us and NIH's transparency approach is feeding right into it.

Intellectual Property and Proprietary Research Risks: IBC discussions frequently involve unpublished research concepts, novel methodologies, sponsor-confidential projects, patent-sensitive information, and emerging technologies. Publicly accessible meeting minutes definitely will expose high-value scientific concepts before intellectual property protections are secured.

Reporting Culture Risks: Extensive public disclosure requirements WILL discourage reporting of near misses, procedural deviations, and low-consequence incidents due to concerns regarding reputation, public misunderstanding, and institutional liability.

Recommendation for reporting:
• Create a centralized national de-identified incident-learning/reporting system.
• Release aggregate lessons learned/concepts rather than institution-specific details.
• DO NOT request any proprietary, export-controlled, classified, client-sensitive, and security-sensitive information from institutions

• Establish NIH (internal) standardized redaction criteria before publishing anything.
• Request minutes for public that highlight oversight actions and outcomes rather than scientific or operational details.

6. Other feedback relevant to this resource: Successful implementation of proposed NIH draft policy will require significantly more guidance than what is currently described in the draft policy. NIH appropriately recognizes that supplemental implementation resources will be needed, but no suggestions are provided as to how to achieve this without additional resources or funding.

NIH must consider and provide guidance on
Scope Determination
• Definitions of covered research.
• Exemptions and exclusions.
• Research versus operational laboratory activities.
• Treatment of assay validation, diagnostics, and service laboratories.
Risk Assessment
• Relationship among Risk Groups, Biosafety Levels, and project-specific risk assessment.
• Guidance for synthetic biology and emerging technologies.
• Criteria for containment determinations and containment reductions.
Transparency and Public Disclosure
• Uniform redaction standards.
• Protection of intellectual property.
• Protection of sponsor-confidential information.
• Protection of security-sensitive information.
• Criteria for public versus confidential records.
Administrative Implementation
• Model Biosafety Assurance documents.
• Standardized protocol forms.
• Renewal and amendment workflows.
• Responsibilities of delegated reviewers.
• Expectations for external or centralized IBCs.

Most importantly, Resource and Workforce Needs:
The proposed policy significantly increases institutional responsibilities including oversight, reporting, record-keeping, training documentation, public posting, and compliance monitoring. NIH must conduct a formal assessment or a dry run of implementation costs and staffing impacts and consider phased implementation and must provide additional funding support. Without additional resources, the policy risks becoming an unfunded mandate that disproportionately affects smaller institutions and biosafety programs.

322. Nils Walter

I am responding: On behalf of myself

Name: Nils Walter

Name of Organization: University of Michigan

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA biophysics, molecular biology and genetics

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's goal of modernizing biosafety oversight through a transparent, scientifically grounded, and risk-proportionate framework. However, I am concerned that the proposed definition of "genetic modification" is overbroad as currently written and could inadvertently bring routine, low-risk research activities within the scope of a policy intended to oversee research involving biohazards.

Specifically, the draft defines genetic modification to include the introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of three criteria, including molecules that "can be transcribed or translated." Because these criteria are joined by "or," this language appears to encompass nucleic acids that are transiently introduced into cells and expressed without replication, integration, or any stable alteration of the recipient genome.

This interpretation would potentially classify routine transient transfection with non-replicating plasmids, the introduction of exogenous messenger RNA (mRNA) for transient protein expression, and research involving non-replicating nucleic acid-based vaccine technologies as genetic modification. Such activities are fundamental to contemporary molecular biology, RNA biology, cell biology, biotechnology, and vaccine research. Transient expression of a protein does not, by itself, constitute a stable genetic modification of the recipient cell, nor does it necessarily introduce a biohazard.

The distinction is scientifically consequential. Nucleic acids differ substantially in their capacity for replication, integration, persistence, and alteration of cellular or organismal properties. Their potential risks depend on their sequence and biological function, the properties of the delivery system, the recipient cell or organism, the duration and consequences of expression, and the experimental manipulations involved. The ability of a nucleic acid to be transcribed or translated, considered in isolation, is not an adequate indicator of biohazard potential.

The proposed definition could therefore create unnecessary uncertainty for investigators, institutional biosafety committees (IBCs), and research administrators. Even if many such activities ultimately qualify

for streamlined review, as contemplated elsewhere in the draft policy, ambiguity about whether routine experiments constitute genetic modification could increase administrative burden, produce inconsistent institutional interpretations, and divert biosafety resources from research presenting more substantive risks.

There are also broader implications for public communication and trust. Conflating transient expression of exogenous RNA with genetic modification may reinforce misconceptions about the nature of RNA research and recombinant vaccine technologies. Clear, scientifically accurate terminology is particularly important in areas of research that have direct implications for public health. Biosafety policies should distinguish genuine biological hazards from molecular techniques that are widely used and can be conducted safely under appropriately calibrated laboratory practices.

I recommend that NIH clarify and revise the definition before finalizing the policy. In particular, the definition should distinguish among:

1. Stable genetic modification, involving heritable or persistent genomic alterations, including integration and genome editing;
2. Replication-competent nucleic acid systems, including constructs capable of one or more cycles of replication in the relevant host cell or organism; and
3. Transient nucleic acid expression, involving non-replicating, non-integrating nucleic acids that may be transcribed or translated but do not themselves produce a stable genomic alteration.

The third category should not automatically constitute genetic modification for purposes of this policy solely because the introduced nucleic acid can be transcribed or translated. Instead, such research should be subject to oversight proportionate to its actual biological properties and experimentally defined risks. Appropriate oversight would, of course, remain warranted when the introduced material, encoded product, delivery vehicle, or experimental procedure presents a relevant biological hazard.

NIH should also clarify the intended relationship between this definition and the draft policy's provisions for delegated IBC review of plasmids and replication-incompetent, non-integrating viral vectors expressing reporter genes or low-risk transgenes. Explicitly addressing transiently introduced mRNA and other non-replicating expression systems would help ensure consistent implementation across institutions and experimental platforms.

A corrected phrase could, e.g., simply combine the two statements:
- Have the potential for one or more cycles of replication in a cell; or
- Can be transcribed or translated
into:
- Have the potential for one or more cycles of replication in a cell and can be transcribed or translated

Finally, I encourage NIH to further evaluate the operational implications of the proposed definition with experts in molecular biology, RNA biology, gene delivery, vaccine development, and institutional biosafety. The objective should be a definition that is mechanistically precise, readily interpretable, and proportionate to risk.

A modern biosafety policy should provide robust oversight of genuinely hazardous biological research while avoiding unnecessary regulatory ambiguity for routine, low-risk research. Revising this definition would advance both objectives, preserve institutional resources for higher-risk activities, and support public confidence in biomedical research and its applications.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support a tiered oversight framework that assigns review and approval responsibilities according to the potential biological risk of the research. Federal review should be reserved for activities presenting substantial risk, significant uncertainty, or implications extending beyond the local institution. For well-characterized, lower-risk research, appropriately trained institutional biosafety committees (IBCs), with delegated review where warranted, are better positioned to make timely, context-specific decisions.

The policy should clearly define the criteria that trigger federal review and provide mechanisms for consistent interpretation across institutions. NIH review should have transparent timelines and a process for resolving disagreements or obtaining timely clarification. The framework should also recognize that biological risk depends on the properties of the agent, the specific genetic modification, the experimental procedure, and the containment environment—not simply on the presence of recombinant nucleic acids. This approach would strengthen accountability while avoiding unnecessary duplication, delays, and administrative burdens for low-risk research.

3. Continued utility of Risk Groups: Risk Groups remain a useful starting point for characterizing the inherent hazards of biological agents, but they should not be used as a substitute for activity-specific risk assessment. Conversely, Biosafety Levels, as described in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), define combinations of containment practices, equipment, and facility requirements; they are not themselves measures of an agent's inherent hazard.

I recommend retaining RG classifications as a baseline while explicitly distinguishing them from the risk assessment needed to determine appropriate BSLs for particular experimental activities. Genetic modification does not invariably increase biological risk, and some modifications may attenuate an agent or render it replication-incompetent. Other modifications may introduce new hazards that warrant additional precautions. NIH should therefore provide clear criteria for evaluating the effects of specific modifications, including relevant evidence of attenuation, replication competence, host range, and biological activity. A transparent, evidence-based process should permit justified adjustments to containment while maintaining appropriate safeguards for genuinely higher-risk research.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I support encouraging voluntary adoption of sound biosafety practices at institutions and in research settings not formally subject to the policy. Effective voluntary compliance is most likely when NIH provides practical guidance, accessible training, model procedures, and proportionate risk-assessment tools that can be adopted without requiring institutions to reproduce the full administrative infrastructure of NIH-funded research programs.

NIH should distinguish clearly between recommended best practices and mandatory requirements, and should avoid creating the impression that non-NIH-funded research is subject to identical obligations when it is not. Outreach through professional societies, biosafety organizations, universities, and other

research networks could promote consistent practices across the broader scientific community. A confidential, nonpunitive mechanism for seeking advice and reporting near-misses would further encourage transparency and learning. Voluntary participation should be designed to build trust and strengthen safety culture rather than inadvertently discourage investigators from sharing information or conducting beneficial research.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed templates could improve consistency, transparency, and institutional learning, but they should be concise, practical, and proportionate to the nature and severity of the event or activity being documented.

For incident reporting, I recommend distinguishing events that pose a credible risk of exposure, infection, or release from minor procedural deviations and near-misses that are appropriately managed locally. The templates should capture the nature and potential consequences of the event, immediate corrective actions, contributing factors, and preventive measures without requiring redundant narrative or information unrelated to risk assessment. Clear definitions of reportable events, reporting timelines, and expectations for follow-up would help institutions apply the requirements consistently.

For meeting minutes, the template should document the substance of the IBC's risk assessment, the rationale for its decision, the required containment and mitigation measures, and any conditions imposed. It should not require unnecessarily detailed reproduction of the protocol or sensitive operational information that does not contribute to meaningful oversight.

Because the draft contemplates public posting of incident reports and meeting minutes, NIH should provide explicit guidance on protecting personally identifiable information, employee and student privacy, confidential medical information, proprietary research, and sensitive security-related details. Standardized redaction procedures and clear criteria for determining what information must be disclosed would help reconcile transparency with privacy, security, and responsible research conduct. NIH should also consider whether the same reporting requirements and level of detail are appropriate for institutions of very different sizes and administrative capacities.

6. Other feedback relevant to this resource: Successful implementation will require clear, accessible guidance that translates the policy's principles into consistent decisions in real laboratory settings. I encourage NIH to develop practical examples and decision trees addressing common research activities, including transient plasmid transfection, exogenous mRNA expression, non-replicating and non-integrating viral vectors, genome editing, recombinant vaccine technologies, and work involving attenuated or replication-incompetent agents. These examples should illustrate how the scope of the policy is determined and how the appropriate level of oversight follows from a documented, activity-specific risk assessment.

Additional guidance would be particularly valuable on the distinction between genetic modification and transient nucleic acid expression; the relationship between RG classification and BSL selection; the criteria for delegated IBC review versus full committee or federal review; and the evidence required to justify changes in containment. Model procedures, standardized terminology, frequently asked questions, and training materials for investigators, IBC members, and biosafety professionals would

promote consistent implementation.

NIH should also provide a reasonable transition period, opportunities for institutions to seek authoritative clarification, and a mechanism for updating guidance as scientific methods evolve. Consultation with researchers across disciplines, institutional biosafety professionals, and institutions with differing levels of administrative resources will be essential. These implementation resources should support a risk-based policy that is scientifically rigorous, predictable, and feasible, while minimizing unnecessary burdens on routine biomedical research.

I support the overall goal of streamlining, simplifying or removing regulations wherever safely possible.

323. Iris Lindberg

I am responding: On behalf of myself

Name: Iris Lindberg

Name of Organization: University of Maryland Baltimore

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): neurogenerative disease; neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope is too wide. The added requrirement for a new IBC application every 3 years adds a significant regulatory burden (I have used the same viruses for 8 years now and it is much easier to simply renew). I strongly recommend permitting renewals.

I also do not think we need to provide additional details on commonly used research viruses, ie AAV2s and lentiviruses. We have been using these reagents for a decade to generate amazing results. There is no emergent biohazard. Section V-C will be especially difficult for IBC offficers to address. (and the idea that a component of a new virus will function as it did in the original virus is incorrect. Current versions of lentiviruses contain parts of other viruses that are *intentionally incapacitated* when reconstituted into the new viral reagent.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Federal oversight should address only REAL risks to human health, ie risk organisms that require handling procedures stonger than Biosafety Level 2 (ie biosafety cabinets). More oversight of BSL2 work will only add a significant regulatory burden for both universities and researchers. Even our own IBC people are telling us this.

3. Continued utility of Risk Groups: The Biosafety Levels outlined in the CDC documents are working well. No need to revise.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Disseminate information on safe handling and current information on KNOWN "likely risky" constructs (ie NOW we know that addition of a furin site specifically to coronaviruses is bad!).

But it is almost certain that all PIs constructing viruses are already aware of this specific construct; and the idea that the federal government could ever assess these risky constructs ahead of time to block their construction is simply not a reasonable assumption.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: none

6. Other feedback relevant to this resource: The current guidelines are adequate. Let's be honest here: if researchers really wanted to make a malignant virus, which they categorically do NOT, they would not report its construction to the IBC ahead of time so that it could be denied via regulation!
And the idea that a local IBC could "catch" the construction of a pathogen ahead of time is simply not feasible.

Adding more regulatation does nothing to keep us safer.

324. Eva Maria Novoa

I am responding: On behalf of myself

Name: Eva Maria Novoa

Name of Organization: CRG

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Currently, definitions of genetic modification require a permanent change to the genetic material of the host cell or organism, for example modification of their genomic DNA (or genomic RNA for select viruses). The new policy language would reclassify any nucleic acid that “Can be transcribed or translated”, including most transiently introduced transfected plasmids, exogenous mRNAs, and several vaccine technologies as a "genetic modification". This re-classification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research and in recombinant vaccine technologies, with potentially devastating public health outcomes.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

325. Jeffrey Farrell

I am responding: On behalf of myself

Name: Jeffrey Farrell

Name of Organization: NICHD Intramural Program

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Developmental Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 2026-10-17-Biosafety-Policy-COmment.docx

Description: Comment on the proposed changes, primarily focused on the need for continued class-wide approvals for some types of research that are determined to be safe

I appreciate the chance to provide input on the new draft NIH Biosafety Policy.

My lab studies how cells get their specific identity during development to empower regenerative therapies that aim to replace particular kinds of cells. We are particularly focused on understanding how the proportion of different intestinal cells is regulated, since this is disrupted in most kinds of intestinal disease. To visualize different types of intestinal cells, we regularly make new transgenic lines that cause that type of cell to glow under a microscope by expressing fluorescent proteins. These plasmids are constructed in standard lab E. coli strains that are non-pathogenic, and neither the plasmid nor the resulting fish line have any components that could affect human health. In fact, fish that have been similarly engineered to express such fluorescent proteins are readily available in pet scores as "Glofish" and pose no risk. To test the role of different genes in regulating the development of different intestinal cell types, we regularly use CRISPR/Cas9 with synthetic guide RNAs to create fish lines where particular genes are disrupted, in order to study their effect. Similarly, this approach poses no risk to the public, since there are no transmissible elements here.

Under the current biosafety protocol, these activities were reviewed in a 'blanket' fashion and judged to pose no risk, and so minor variations do not require re-review. For instance, creating a transgenic fish line that fluorescently labels a cell type was determined to pose no risk, and so I currently do not need to have each individual line we create pre-reviewed when a different color protein is expressed or it is moved into a different cell type. We do not use dual-use reagents or viruses, any components that could be expected to cause human disease, and none of the work that we do with recombinant DNA could be transmissible or affect human health.

Our lab creates up to 100 new plasmids per year, including the intermediates during the process of constructing them as well as a similar number of guide RNAs for CRISPR experiments. Obtaining specific advance approval for each construct or guide RNA would likely take 30 minutes or longer, given the time required to assemble the application, submit it through an online system, and verify the results. This would introduce 100 hours per year of extra administrative burden that could not be handled by administrative assistants, given the technical nature of the documentation, which would be multiple weeks of researcher time taken away from scientific work. This would be approximately $8,000 per year of salary spent on this administrative work.

I agree that stringent oversight is critical for research that has potential biosecurity implications, dual-use implications, or works with potentially transmissible or pathogenic materials. However, for work like ours, this administrative burden will provide no additional safety, since none of the above apply to us, as has been determined by Biosafety

Committee review of our research program. I would be extremely grateful if the NIH preserved exemptions for low-risk activities, where more blanket approvals for categories of safe activities can be granted after stringent biosafety committee review of a laboratory's program. I think this would be in the taxpayer's interest to make sure that the money they spent on science goes toward critical research to help improve human health, rather than potentially ineffective administrative work.

326. John A Bilello PhD

I am responding: On behalf of myself

Name: John A Bilello PhD

Name of Organization: Innovalyst ICaN

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): neuroscience neuro-oncology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: transient expression does not equal gene modification . Transient aaaaaaexpression allows us to rapidly test gene function and protein localization without the time-consuming process of generating stable transgenic lines. This speed is essential for validating constructs and confirming experimental results before committing to longer-term studies.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I do not think federal oversight is required.

3. Continued utility of Risk Groups: Transient expression is not modification. Guidlines are useful but perhaps not useful in this case.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Useful

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Materials were not available to me

6. Other feedback relevant to this resource: I don’t believe that NIH should spend any of it’s resources on regulation of this area of research.

327. Venkat Gopalan

I am responding: On behalf of myself

Name: Venkat Gopalan

Name of Organization: Ohio State University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/17/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: This reclassification specifically covering any nucleic acid that can be transcribed or translated will cover many common applications that do not entail genetic engineering (e.g., protein purification). Transient versus stable introduction of genetic material should be differentiated in this policy. Thank you for reading my comments.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

328. Blake Meyers

I am responding: On behalf of myself

Name: Blake Meyers

Name of Organization:

Type of Organization: Other

Type of Organization - Other: member of the public

Role: Member of the Public

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Gold Standard Science

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support effective biosafety oversight, but I am concerned that the proposed definition of "genetic modification" is scientifically broad. Biosafety policy should use precise biological terminology and establish requirements proportionate to demonstrated risk.

Section II includes the introduction of nucleic acids that can be transcribed or translated, without requiring a stable alteration of the recipient's genome. This conflates distinct biological processes: transient gene expression, infection, and lasting genetic modification.

A common respiratory viral infection illustrates the problem. Viral nucleic acids enter host cells and undergo replication and expression, but describing a person with a cold as "genetically modified" would be misleading. I recognize that this policy concerns laboratory research rather than ordinary community infections. Nevertheless, a definition that invites this interpretation needs revision.

NIH should distinguish stable genomic alteration, transient delivery and expression of nucleic acids, and infection with an unmodified biological agent. Each may warrant biosafety assessment in a research setting, but they should not be treated as interchangeable concepts. Oversight of an infection experiment can be justified by the properties of the pathogen and the procedures involved; it does not require redefining infection as genetic modification.

I am also concerned about the public consequences of this terminology. An authoritative federal policy should improve understanding of genetics, biotechnology, and infectious disease. Language that blurs these distinctions could instead reinforce misconceptions and politicize subjects that require careful scientific explanation.

I urge NIH to revise this definition before finalizing the policy, clearly identify the hazards each category is

intended to address, and explain the evidence supporting the proposed scope. Genetic modification should not itself be used as a substitute for identifying a credible mechanism of harm.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Oversight should be calibrated to the actual hazards of an experiment, including pathogenicity, transmissibility, toxicity, exposure routes, scale, and available containment measures. The presence of introduced nucleic acids alone is not a sufficient measure of risk.

NIH should provide explicit exemptions or streamlined institutional determinations for well-characterized activities presenting negligible biosafety risk. Delegating review can reduce committee workload, but it does not eliminate the burden of preparing, processing, and maintaining approvals.

Before expanding mandatory oversight, NIH should explain what safety gap each additional requirement addresses and assess its likely benefits against its administrative costs. Unnecessary review can consume the same investigator and biosafety personnel time needed to evaluate consequential hazards.

The final policy should strengthen the capacity to recognize and manage meaningful risks while preserving efficient conduct of low-risk research. Scientific evidence and proportionate safeguards should determine the requirements.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

329. Kate Keller

I am responding: On behalf of myself

Name: Kate Keller

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): vision research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of work regarding use of human primary cells is not well defined. I have been working with primary human cells for 20+ years. They are critical to my work on deciphering how glaucomatous cells are different from healthy cells.
We get eye tissues from the eyebank, who have their own set of rules that they adhere to about who's eyes can be donated for transplant and research. These are well-defined and follow strict regulation at the Federal level. Moreover, we also exclude eyes from donors with certain conditions e.g. sepsis, that could pose risk to personnel in our labs.
If we have to start screening for adventitious agents the financial cost and time spent screening each of our cells would cripple much needed research in my lab. The proposed changes don't even define which agents I am meant to screen for.
I realize that the importance of preventing spread of disease and the health of our research workers, but this policy does little above what we already do to keep them safe. It just causes unnecessary burden for scientific research. NIH is pushing the use of NAMs to reduce animal work and these proposed changes make it more difficult to make this change.
Importantly, NIH needs to define "adventitious agent"

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed changes seem to over-burden folks at the local level, with no help from the Federal level to alleviate the increased administrative and financial burdens that come with these proposed changes.

3. Continued utility of Risk Groups: As I already mentioned above, NIH needs to define "adventitious agent". If we do not know what we need to screen for, then we're uncompliant. There is research already being done using viruses to deliver gene therapies to the eye (e.g. FDA-approved Luxturna), which are helping humans see again. Not all genetically modified agents are bad. There needs to be careful consideration about those modifications that can help, from those that cause harm. Again, the definitions and guidance from the NIH are critical in determining this at a local level.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It's very unclear how you will separate minor events from those that are of real concern. There needs to be much more thought and guidance into how researchers should document incidents that support accountability without compromising research security or mischaracterizing minor indicents.

6. Other feedback relevant to this resource: If these guidelines are adopted, it is going to take much longer than 6 months to implement at the local level. Institutional policies will need to be updated, personnel will need to be trained, IBC will need to be expanded with knowledgeable personnel, etc, etc. Again, this is placing undue burden at the local level without support from the Federal level. NIH / DDS will need to publish practical implementation tools before any implementation can be done at the local level. This all takes time and I do not see how this can be done in the proposed 6 month timeline.

330. Darren Boydston

I am responding: On behalf of myself

Name: Darren Boydston

Name of Organization: National Heart Lung and Blood Institute

Type of Organization: Government Agency

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Currently, definitions of genetic modification require a permanent change to the genetic material of the host cell or organism, for example modification of their genomic DNA (or genomic RNA for select viruses). The new policy language would reclassify any nucleic acid that “Can be transcribed or translated”, including most transiently introduced transfected plasmids, exogenous mRNAs, and several vaccine technologies as a "genetic modification". This re-classification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research and in recombinant vaccine technologies, with potentially devastating public health outcomes.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Currently, definitions of genetic modification require a permanent change to the genetic material of the host cell or organism, for example modification of their genomic DNA (or genomic RNA for select viruses). The new policy language would reclassify any nucleic acid that “Can be transcribed or translated”, including most transiently introduced transfected plasmids, exogenous mRNAs, and several vaccine technologies as a "genetic modification". This re-classification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research and in recombinant vaccine technologies, with potentially devastating public health outcomes.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

331. Mariano Garcia-Blanco

I am responding: On behalf of myself

Name: Mariano Garcia-Blanco

Name of Organization: University of Virginia

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA Biology, virology, immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The term 'genetic manipulation' is incorrectly used reflecting what has become evident lack of expertise at the NIH leadership level. You need to let scientific experts help you achieve the type of biosecurity you are seeking without crafting policy proposals that are flawed. You are NOT helping the American citizenry with this type of proposal.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

332. Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

I am responding: On behalf of myself

Name: Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 4-Biosafety-Policy-Comments-to-NIH-OSP-v2.docx

Description: Comments regarding NIH Biosafety Policy Draft

Priority requests to NIH OSP Regarding Biosafety Policy Draft

- **<u>Certify Instutional Biosafety Program Compliance with Policy.</u>**

  1. Certification of **compliance** with the new NIH Biosafety Policy, and **confirmation of programmatic structure**, institutional **empowerment of Biosafety Program**, and **leadership position of Biosafety Officer** must become part of the grant application. Similar to animal program section.

- **<u>Define the minimum requirements for an Instutional Biosafety Program.</u>**

  1. Partial quote: '*. . . the National Institutes of Health (NIH) is committed to ensuring that* ***gold-standard science*** *is conducted under* ***gold-standard biosafety conditions****.*"
  A single, egregious oversite is that the requirement for a "Biosafety Officer" defaults to that listed in the current NIH Guidelines. How can an institution empower and run a "**gold-standard biosafety program"** without mandating a program lead that has significant biosafety experience?

  2. Pick a consistent title for the policy that reflects what the NIH wants / needs: Is this a "Biosafety Policy", a "Biosafety & Biosecurity Policy", or a "Policy for work with Biohazards"? Each of the titles will be interpreted differently by institutional leadership.
  This is important because the draft title "***Biosafety Policy for Research Involving Biohazards"*** (Biosafety & Biosecurity Policy?) does not address the fact that biosafety programs include a comprehensive administrative portfolio that includes research safety, compliance, ethics, training, committee review, and approval portfolio.

  3. Define what level of institutional empowerment must be granted to the Biosafety & Biosecurity program. Must both components be supported or is either one, biosafety or biosecurity, adequate to satisfy this policy?
  A biosafety officer or biosafety professional overseeing this gold standard biosafety program must be granted administrative level empowerment equivalent to the "Director of Animal Welfare", Director of Human Research Protections" or the "Institutional Veterinarian". A more appropriate role, to accomplish what the NIH is striving toward, will be Assistant or Associate Vice Provost or Vice President for Biosafety & Biosecurity Programs. Someone at the institutional leadership level, with appropriate biosafety experience, must be empowered to oversee these programs. **This must be mandated by the policy or it won't**

happen. Lack of this empowerment is currently what fails many biosafety programs.

- **Codify the Institutional Biosafety Committee (IBC)**

  1. Define what level of institutional support is adequate to satisfy policy requirements. Must Institutional resources include similar administrative structure for the IBC that is offered to the IRB and/or IACUC? What is the minimum? Office space, administrative support adequate for the number of IBC committees (or sub-committees), Leadership team consisting of Director, Associate Director, Professional staff separate from the biosafety program? For example, the Director of the IBC office has a separate role from Institutional Biosafety Officer, etc.? The Biosafety Officer sits as a voting member only?

- **Fully Embrace Risk-Based Biosafety**

  1. It is stated that this policy intends to encourage and embrace risk-based oversight and reporting. Yet, the only risk criteria incorporated into this first draft are Biological Agent Risk Groups and Biosafety Levels. These criteria are not applicable to all life science research activities or agents proposed for enhanced biosafety oversight. For example, biologics used in clinical trials cannot be defined by a biological agent Risk Group. Biologics are typically risk assessed by Risk Banding. Include/acknowledge this aspect of risk assessment in the updated draft. Alternatively, allow the biosafety professionals overseeing biosafety programs the freedom to perform risk assessment without specifying the risk criteria that must be used, because in biosafety and especially because of rapidly developing life sciences research programs, "it depends". Please let life science research professionals do what they do best, without restriction.

- **Risk-Based Biosafety**

  1. Since Biosafety Oversight mandated by the New NIH Biosafety Policy is supposed to be risk-based, registration, IBC review, and reporting of Biosafety Level 1 (BSL-1) or biologics band 1, materials and research, is a **NO GO**. Please exempt these low-risk materials from the Policy.

333. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Professional Biosafety Organization

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 3-NIH-Biosafety-Policy-Comments-1.docx

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public confidence in NIH-supported science. I offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

Topic to Address*: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any

resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.

3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory

rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:
    a. the nature and stability of the genomic modification;
    b. whether the modification is heritable and the potential for transmission through breeding;
    c. effects on animal health, phenotype, host range, susceptibility, or disease;
    d. potential entry into breeding or food-production systems;
    e. potential environmental release or interaction with non-research animal populations;
    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and
    g. applicable federal, state, or other regulatory oversight.
2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.
3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.
4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

  deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the

Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

b. State explicitly that the Policy does not address non-biological hazards.

c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

  Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

  the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate, and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

  Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and

Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

I believe the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, I request that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, I welcome the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. I do not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. I recommend that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice

- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, I recommend a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with my earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*
- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. I recommend that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior

leadership;

2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply

another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.
NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, I kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. I encourage NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE

BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The

Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While I support appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes
6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions

throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as “any incident,” “loss of containment,” “significant problems,” and “minor spills... generally do not need to be reported,” and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report “potential releases involving facility and/or equipment failures even when redundant systems were functioning properly” would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure

in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: I recommend the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and

occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. I support preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

334. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 2-Feedback-NIH-Comments-1.docx

Comment to NOT-OD-26-112

I appreciate NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions.

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk

and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under

the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure,"

“compliance violation,” and “minor spill.” The policy should clarify whether precautionary post exposure prophylactic treatment is considered “agent-specific treatment”. It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

5. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures,

workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

Recommend that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

335. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 1-Recommendations-to-the-NIH-OSP-1.docx

I ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

1. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts;

compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

2. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure

implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological

exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

3. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

4. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

5. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

6. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and

explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

7. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions.

Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

336. Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

I am responding: On behalf of myself

Name: Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Institutional Biosafety Officer & Director of IBC

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 5-My-Edited-NIH-Policy-Comments.docx

Description: Commentary provided during Listening Session #1

NIH Hearing Comments (296 words)

Andrew Maksymowych, Biosafety Officer at the University of Pennsylvania.

These opinions are my own and do not necessarily represent the views of my employer

(1) The designation "Biosafety Modernization Initiative" is presumptuous. The Biosafety profession existed before the *NIH Guidelines* and will exist with or without guidance from the NIH.

(2) Science and technology have evolved, and the Biosafety profession has endeavored to keep pace. Programs do not exist exclusively to support the *NIH Guidelines*.

(3) Biosafety professionals are practicing "risk based" biosafety. It is the *NIH Guidelines* that have been stuck in the past. With that perspective this initiative is overdue and welcome.

(4) 21 Century Biosafety is not currently defined, nor will it be in the future, strictly by the NIH Policy. The OSP acknowledged that other Federal agencies may have different expectations for biosafety, independent from the new NIH Policy.

Step one, must be to define programmatic pillars for this policy:

(5) **Harmonization:** Will new NIH Policy be harmonized with international biosafety standards?

(6) **NIH Policy:** Must not confound the practice of biosafety.

(7) **Institutional Biosafety Committees:** Have evolved to address biosafety risk assessments beyond narrowly addressing NIH guidance. Are there expectations for significant operational changes?

Will the NIH detail expectations regarding IBC status within institutional compliance committee hierarchy, mandating institutional support and provision of adequate resources?

(8) **The Biosafety Profession:** Empowerment for Biosafety Programs from the NIH is welcome. What this may look like remains to be defined and must be coordinated by biosafety professionals.

(9) **Finally:** "Because we are dealing with the federal government" only Leadership is empowered to pursue such interactions. Guard against persistent tendencies for policy activities such as this to be appropriated by leadership. Consider preferentially, input from biosafety profession "boots on the ground".

Thank you!

337. Kristin Koutmou

I am responding: On behalf of myself

Name: Kristin Koutmou

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): University of Michigan

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed NIH biohazards-policy language is harmful because it expands "genetic modification" far beyond its conventional meaning. Genetic modification generally implies a stable or permanent alteration to an organism's genetic material. Under the proposed definition, however, any introduced nucleic acid that "can be transcribed or translated" could qualify—even when it does not integrate into the genome or create a lasting genetic change.
This would sweep routine and often transient research tools into the same category as genome-altering technologies. Examples could include transfected plasmids, exogenous messenger RNA (mRNA), and several recombinant vaccine platforms. Treating these fundamentally different technologies as equivalent would:

1) Create scientific and regulatory confusion by blurring the distinction between transient gene expression and stable genomic alteration.
2) Impose unnecessary oversight and administrative burdens on common research methods that do not permanently modify genomes.
3) Produce inconsistent interpretations and compliance decisions across institutions and Institutional Biosafety Committees.
4) Mislead the public into believing that routine RNA research or certain vaccines permanently alter a person's DNA.
5) Undermine trust in biomedical research and vaccination, reinforcing existing misinformation about mRNA and recombinant vaccine technologies.
6) Delay research and public-health responses by subjecting well-established, comparatively low-risk methods to requirements designed for genuinely genome-altering work.

A scientifically sound policy should distinguish among temporary expression, replication-capable nucleic acids, and stable genomic changes, with oversight proportional to each technology's actual biological risk. Without those distinctions, the proposed definition could hinder research while producing little

corresponding biosafety benefit—and could have serious downstream consequences for vaccine confidence and public health.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: This change in language absolutely should not be adopted, it has the potential to would bring to a staggering halt all fundamental RNA and DNA research in the U.S.

338. Robert Gallant

I am responding: On behalf of myself

Name: Robert Gallant

Name of Organization: IAVI

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Antibody and vaccine development

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Thank you for the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. I support NIH's efforts to strengthen biosafety oversight and recognize that transient nucleic acid expression can pose significant risks that require careful review.

My concern is that the proposed definition of "genetic modification" groups permanent changes to the genome together with transient expression. Both warrant oversight, but they present distinct safety considerations that should remain explicit in the policy.

Permanent genomic modification raises concerns about unintended genetic changes and their persistence in cells and their descendants. Transient expression using mRNA, nonintegrating DNA, or self-amplifying RNA raises distinct concerns such as the amount and duration of expression, the cells and tissues affected, immune responses, and the effects of the delivery system and expressed product. These approaches differ from one another and should not be treated as interchangeable.

When transient expression does not alter the genome, it can reduce some risks associated with permanent modification. This does not mean that transient expression is always safer or that its effects are necessarily temporary. For example, transient delivery of gene-editing machinery can still produce permanent genomic changes. The important point is that each approach requires assessment of its specific risks.

Although this policy addresses research biosafety, NIH's terminology may influence how these technologies are understood elsewhere, including by drug regulators. A broad definition without clear distinctions could make it harder to assess and communicate the risks that matter for patient safety.

I encourage NIH to distinguish permanent genomic modification from transient expression, through clear subcategories. This would preserve appropriate oversight while making clear that inclusion under the same policy does not imply the same biological effects, risks, or regulatory needs.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

339. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): molecular biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As written, the draft policy is overbroad in its definitions of what needs extra oversight. By including "introduction of nucleic acids that:
can be transcribed or translated,
can replicate,
can cause stable genomic alterations,
and also includes genomic changes introduced through passaging, reassortment, chemical mutagenesis, or radiological means," it captures much of the basic biology research that is very common and safe in research labs. We have 50+ years of data demonstrating the safety of introducing engineered vectors into cells to understand both normal biology and disease processes. I suggest being more specific to focus on the intended target which is presumably generating anything that would harm humans rather than everything that happens in a molecular biology, biochemistry, genetic, pharmacology, cell biology, etc. research setting

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

340. Duke University

I am responding: On behalf of an organization

Name: Jennifer Lodge

Name of Organization: Duke University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Duke University

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Duke-Response_NIH-Proposed-Biosafety-Policy-Draft.pdf

Description: Duke University submission, compiled by subject matter experts in the Biological Safety Division of the Duke Occupational and Environmental Safety Office.

Duke | OFFICE for RESEARCH & INNOVATION

October 18, 2026

Office for Science Policy
National Institutes of Health
Bethesda, MD 20892

RE: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Reviewing Officials:

Duke University appreciates the opportunity to provide comments on the draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112). Duke is a private research university with a major academic medical center and one of the nation's largest academic research enterprises. As a member of COGR, Duke would like to note that we endorse the letter submitted by that organization.

Subject matter experts in the Biological Safety Division of the Duke Occupational and Environmental Safety Office reviewed the draft policy and compiled the following comments. The concerns outlined below could reduce researcher safety and slow scientific advancement in the United States by introducing unnecessary regulatory burdens and creating fear among scientists. The areas of greatest concern are as follows:

1. **Public Posting of Identifiable Information**
   The draft NIH policy requires public posting of IBC meeting minutes without redacting information such as Principal Investigators' (PIs) names, biological agents, grant numbers and other information. Notably, the requirement to post IBC meeting minutes has been in place since June 2026. When carefully implemented, such measures help the public understand how the IBC deliberates the risks associated with biomedical research and recommends appropriate biocontainment practices. While Duke supports such transparency, we are concerned that the new requirement to publicly post incident reports will have an adverse impact in discourage reporting, therefore creating an unintended safety risk.

   NIH proposes requiring incidents to be reported using a standardized template. Although the template states that personally identifiable information should not be reported, it requires the PI's name, grant number, general location and position titles of involved individuals. Providing the foregoing information could allow individuals to deduce the location where IBC covered work is taking place, as well as the individuals involved. This not only presents public safety risks if individuals with nefarious intent seek to target locations where IBC work is occurring, but also the safety of the individuals involved. A chilling effect on reporting will limit biosafety professionals' ability to assess individual incidents, recommend mitigation measures, monitor trends and develop awareness and training initiatives that reduce injuries and exposures.

These fears are not unfounded. Researchers have faced well-documented threats from activist groups. If NIH proceeds with the proposed incident reporting requirements, it should strongly consider an anonymized, aggregated reporting system, with access to identifiable information restricted to authorized users who have a legitimate need to know and whose access can be tracked.

Additionally, under the current draft, all Select Agent work would require IBC review, be documented using the required template, and be subject to public posting. These changes raise concerns about consistency with the biosecurity measures required under federal select agent regulations to prevent unauthorized access to restricted select agents and toxins. As noted above, PI names and associated location information could link personnel to laboratories. Making this information publicly available is inconsistent with regulatory precedent, which seeks to impose the utmost security parameters around Select Agent projects.

Requiring standardized templates for IBC meeting minutes and incident reports, combined with mandatory public posting, provides information publicly that would be accessed efficiently by adversaries to the U.S through automated tools and sophisticated machine learning capabilities, resulting in a loss of US based and funded intellectual property. These cyberbiosecurity concerns, combined with potential physical security concerns, substantially expand institutions' exposure to attacks and increase the vulnerability of the American scientific enterprise.

2. **Unfunded Administrative Burden**

The draft policy significantly expands IBC responsibilities compared with the current NIH Guidelines and introduces more prescriptive recordkeeping requirements. The scope of biological materials requiring IBC review would expand to include all wild-type organisms, all toxins and all genetically modified cells, viruses and organisms. Previously, this scope was limited to a defined subset of recombinant or synthetic nucleic acids.

Institutions have historically relied on biological safety professionals as subject matter experts to review research, conduct risk assessments and recommend mitigation measures to ensure safe research practices. This expert review has enabled institutions to address biological hazards in the workplace as they arise without delaying research through review by a committee that meets periodically, often monthly. The proposed changes will deflect those limited resources that historically focused on higher- risk research, to review research activities that pose little risk, thus creating delays in the advancement of science.

Additionally, the draft policy limits each registration approval to three years, after which an entirely new registration must be submitted and approved. This would substantially increase the number of registrations requiring full review on a recurring basis without a corresponding benefit since existing mechanisms at many institutions encourage updates more frequently than every three years, making mandatory expiration and full resubmission unlikely to provide meaningful additional risk reduction.

3. **Conditional Recordkeeping Requirements**

The recordkeeping requirements tie IBC records, including meeting minutes and incident reports, to individual grants and stages in their lifecycles.

An individual IBC registration may support multiple grants with different end dates and retention requirements, while a single set of meeting minutes may document decisions concerning several registrations. Linking retention requirements to individual grant lifecycles therefore creates uncertainty about which retention period governs these shared records. NIH should establish a clear baseline retention period for IBC records and clarify how institutions should apply longer grant-specific requirements when records cover multiple projects or funding sources.

Duke respectfully urges the NIH incorporate community feedback before finalizing the draft Biosafety Policy for Research Involving Biohazards. Any changes should address concerns related to research safety and impacts to scientific advancement in the U.S.

On behalf of Duke University, I appreciate the opportunity to comment on this proposed policy. I would be most willing to continue discussing matters related to these considerations.

Respectfully submitted,

[redacted]

Jennifer Lodge, Ph.D.
Vice President for Research & Innovation
John Stohbehn University Distinguished Professor
Professor of Molecular Genetics and Microbiology
Duke University

341. Marie-Luise Winz

I am responding: On behalf of myself

Name: Marie-Luise Winz

Name of Organization: Johannes Gutenberg-University Mainz

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA Biochemistry

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I would like to comment on the definition of Genetic Modification. The way the new draft is phrased, it defines not only the stable introduction of a DNA alteration as a genetic modification, but also the transient introduction, e.g., of an mRNA, which meets the criterion of being 'translatable'. I believe this to be factually wrong and misleading, as such an introduction does NOT alter the genome, and an mRNA that is introduced will not be stably present in the cells.
Defining such an introduction as a genetic modification will almost certainly (further) erode the public trust in routine RNA research, as well as in RNA-based treatments and vaccines, with adverse public health outcomes due to reduced funding and reduced public acceptance.
Even as a non-U.S. researcher, not undertaking NIH-funded research, I believe such a change in policy to potentially have consequences also for global research. Therefore, for the benefit of U.S. and global research, I would invite the NIH to refrain from introducing the criterion 'Can be transcribed or translated' as part of the definition of Genetic Modification.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

342. The University of Auckland

I am responding: On behalf of an organization

Name:

Name of Organization: The University of Auckland

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The overall objective of establishing a comprehensive biosafety policy for research involving biohazards is supported. However, the policy should explicitly recognise that institutions outside the United States may already be subject to robust national legislative and regulatory oversight frameworks.

In New Zealand, biological hazards are managed through a combination of statutory and institutional controls, including the Biosecurity Act 1993, Hazardous Substances and New Organisms Act 1996, Health and Safety at Work Act 2015, Environmental Protection Authority approvals, and institutional biosafety governance processes. Similar frameworks exist in many other countries.

The policy should therefore clarify that oversight requirements are intended to complement, rather than duplicate, equivalent national regulatory systems. Foreign institutions should be permitted to demonstrate compliance through existing national oversight arrangements where these achieve equivalent biosafety outcomes.

The proposed scope would create an additional oversight burden for research activities that are not funded by NIH but occur within institutions that receive some NIH funding. Applying NIH biosafety obligations across all institutional research regardless of funding source could extend the policy beyond its intended purpose and create unnecessary duplication where risks are already managed by national regulators.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered and risk-based oversight model is appropriate and supports the efficient allocation of regulatory and institutional resources.

Oversight should be proportionate to the nature and magnitude of risk, with higher-risk activities receiving greater scrutiny and lower-risk activities managed through institutional processes. Local biosafety committees and institutional governance bodies are often best positioned to assess specific research activities, local facilities, workforce capability, and operational controls.

For international institutions, tiered oversight should explicitly recognise the role of national regulators and existing legal obligations. Federal NIH requirements should focus on matters directly relevant to NIH-funded research and should not duplicate reviews, approvals, reporting, or containment determinations already required under national regulatory systems.

A key principle should be subsidiarity: oversight should occur at the most appropriate level, with NIH requirements addressing genuine gaps rather than replicating existing controls.

3. Continued utility of Risk Groups: Risk Groups should continue to be used as the starting point for biological risk assessment. Risk Group classification provides an assessment of the inherent hazards associated with an organism and remains a useful foundation for evaluating biological risk.

However, containment requirements should not be determined solely by an organism's Risk Group or through automatic assignment of a Biosafety Level. Effective biosafety management requires a broader risk assessment that considers the specific activities being undertaken, including:
• The nature of the experimental procedures.
• Scale and volume of work.
• Potential exposure pathways.
• Routes of transmission.
• Environmental considerations.
• Competency and training of personnel.
• The impact of any genetic modifications on the organism's risk profile.

This approach is consistent with the principles set out in the WHO Laboratory Biosafety Manual and aligns with the risk assessment framework used in New Zealand containment standards, where risk assessment is the primary determinant of appropriate containment measures. Under these frameworks, Risk Group classification informs the assessment but does not, by itself, prescribe the containment level required for a particular activity.

This distinction becomes particularly important for genetically modified organisms. Genetic modifications may increase, decrease, or otherwise alter risk in ways that cannot be adequately captured through organism classification alone. Consequently, containment decisions should be based on a comprehensive assessment of the modified organism and the proposed work rather than a predetermined linkage between Risk Group and containment level.

An additional consideration for international institutions is the proposed role of the Biosafety and Containment Steering Committee (BCSC) in determining or approving containment requirements. Where the policy contemplates referral of containment decisions to NIH bodies, a framework in which overseas institutions must seek NIH approval for containment determinations that are already subject to established national regulatory and institutional processes should be avoided.
In New Zealand, containment requirements for regulated organisms are determined within a legislated framework that includes Environmental Protection Authority approvals, applicable containment standards, institutional biosafety expertise, and activity-specific risk assessments. Institutional Biosafety Committees and subject matter experts are expected to exercise professional judgement within these

legal requirements. Requiring external approval of containment decisions would create uncertainty regarding regulatory accountability and could conflict with obligations under national legislation.

While consultation, advice, and guidance from NIH may be valuable, the policy should recognise the authority and competence of equivalent institutional and national oversight systems outside the United States. International institutions should retain the ability to determine appropriate containment measures through their own regulatory and governance frameworks, provided these achieve outcomes consistent with the objectives of the NIH policy. The role of NIH committees should therefore be advisory or limited to clearly defined circumstances, rather than becoming a routine approval pathway for containment decisions that are already governed by national regulatory requirements.

A risk-based approach that uses Risk Groups as an initial input, while determining containment requirements through activity-specific assessment, is likely to provide greater scientific rigour, flexibility, and proportionality than an approach that relies primarily on Biosafety Level designation.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH biosafety resources and guidance documents provide valuable reference material that may assist institutions beyond the formal scope of the policy.

However, adoption of these requirements outside NIH-funded research should remain voluntary. Guidance intended for non-NIH-funded research should not become an indirect prerequisite for institutional eligibility to receive NIH funding or participate in NIH-funded collaborations.

Voluntary uptake is most likely where NIH provides:
- Practical guidance documents.
- Model policies and templates.
- Training materials.
- Case studies and examples of good practice.
- Flexible implementation approaches that can be adapted to local regulatory environments.

Institutions should retain discretion to adopt NIH guidance where it adds value and aligns with national regulatory frameworks.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The development of standardised incident reporting and meeting documentation templates has the potential to improve consistency, transparency, and institutional learning across the research sector. Standardisation can support clearer communication of biosafety issues and facilitate oversight where required.

However, the implementation framework should allow sufficient flexibility to accommodate differing governance models across institutions, particularly large and complex organisations.

Many institutions now manage incident reporting and investigation through central Health and Safety functions rather than through Biosafety Committees alone. This approach should not be interpreted as a weakness in biosafety governance or a failure of institutional oversight. In many cases it is an operational necessity driven by organisational size, the volume of incidents and near misses managed across

multiple hazard domains, and the need to maintain efficient, professional investigation and corrective action processes.

Under these models, Biosafety Committees often retain responsibility for policy, oversight, specialist advice, and review of significant biosafety matters, while day-to-day incident management, investigation, corrective actions, trend analysis, and organisational reporting are undertaken through established Health and Safety systems. This integrated approach can improve consistency and ensure that biological hazards are managed alongside other workplace risks within a unified risk management framework.

The policy and associated templates should therefore accommodate equivalent governance arrangements and focus on outcomes rather than prescribing a specific organisational structure. Institutions should have flexibility to demonstrate that appropriate biosafety expertise, oversight, and escalation pathways exist, regardless of whether routine incident management is administered through a Biosafety Committee, a Health and Safety function, or a combination of both.

For international institutions, the reporting framework should also recognise differences in legal and regulatory requirements regarding information collection, disclosure, and retention. Particular consideration should be given to:
• Privacy and data protection obligations.
• Commercially sensitive information.
• Intellectual property considerations.
• Confidential research information.
• National security restrictions.
• Legal obligations imposed by foreign regulators.

The policy should clearly specify:
• The minimum information required for reporting.
• How submitted information will be protected and stored.
• Circumstances in which information may be disclosed.
• Circumstances where foreign institutions may appropriately redact or withhold information.

Where information has already been reported to a competent national authority, NIH should also consider mechanisms that minimise duplicate reporting requirements while ensuring that the objectives of institutional learning and oversight are achieved.

6. Other feedback relevant to this resource: Implementation guidance for international institutions would be particularly beneficial.

Institution-wide application of NIH biosafety requirements will create substantial administrative and resource implications for overseas organisations, including increased biosafety review activities, training requirements, record-keeping obligations, reporting responsibilities, and governance costs. Without careful calibration, these costs will be borne by institutions and funding sources that receive little or no direct NIH support.

To support practical implementation, NIH should consider developing additional guidance that:

• Clarifies how equivalent foreign regulatory systems will be recognised.
• Explains how NIH requirements interact with existing national laws and regulatory approvals.
• Provides examples and case studies relevant to international institutions.
• Identifies circumstances where compliance with national regulatory requirements may satisfy NIH expectations.
• Reduces duplicative reporting where information has already been provided to competent national authorities.
• Clearly defines the extent to which institution-wide obligations apply to non-NIH-funded research conducted within NIH-funded organisations.

Such guidance would improve consistency, reduce uncertainty, and support effective implementation across the international research community.

343. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: It is recommended that NIH maintain the previously established categories of exempt research. NIH describes the purpose of the modernization as expanding oversight to biohazards while "removing red tape for low-risk research" and specifically asks commenters whether the proposed tiered oversight is appropriately calibrated to risk and administrative burden.

Exempt from IBC oversight is not synonymous with exempt from safe laboratory practice. Rather, it represents a determination that the incremental safety benefit of mandatory IBC oversight does not justify the administrative burden for a defined class of low-risk research. Currently exempt research was previously determined by NIH, following notice and opportunity for public comment, not to present a significant risk to health or the environment.

The scope of work with primary and well established cell lines that requires review is unclear. As written, "may be contaminated" could be interpreted to include virtually any primary human or animal cells (including any research involving NHP cells or tissues) for which the infectious-agent status of the source has not been comprehensively established.

NIH should define "adventitious agent," establish a risk-based threshold for determining when contamination is reasonably anticipated, and clarify whether donor screening, testing, source information, or other documentation can establish that primary cells do not fall within this category. The Policy should also clarify its application to commercially obtained cells, repository specimens, patient-derived cells, and primary animal cells and provide examples of included and excluded materials. A merely theoretical possibility of contamination should not independently trigger IBC oversight; the definition should be tied to a known or reasonably anticipated potential hazard to human health. Clear criteria are necessary to avoid additional administrative burden by unnecessarily expanding IBC oversight beyond research presenting a meaningful biosafety risk.

Additionally, The Policy does not provide sufficiently objective criteria for determining when a cell line

qualifies as well-characterized, creating the potential for inconsistent interpretations among investigators, biosafety professionals, and IBCs. NIH should specify what level of information regarding identity, provenance, biological characteristics, and adventitious-agent testing is necessary; whether established commercially available or widely used cell lines may be presumed to satisfy the definition; and how primary, immortalized, genetically modified, and patient-derived cells should be treated. NIH should also provide examples of included and excluded cell lines. Because this determination may affect the scope and level of institutional oversight, a clear, risk-based definition is necessary to ensure consistent implementation and avoid additional administrative burden by unnecessary review of research that does not present a meaningful biosafety risk.

Section IV-2 outlines the only clinical research provision and specifically identifies IBC review for biohazards that shed, replicate, integrate, require higher-risk manipulation, or involve RG2 or higher wild-type agents. There is no discussion of other genetically modified agents being used in clinical research, such as plasmids or RNA, and no discussion of exemptions. Given the https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative.html, additional administrative burden should not be introduced by expanding IBC oversight in the clinical research arena.

The Policy should also exempt any covered clinical research studies from mandatory three-year de novo IBC review or permit an administrative continuation process confirming that no material changes affecting biosafety have occurred. Full IBC review should be required only for clinical research presenting local biosafety risk, where there may be questions regarding product handling and possible shedding. This approach would maintain appropriate biosafety oversight while reducing unnecessary regulatory burden.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The incorporation of delegated review has the potential to decrease regulatory burden and expedite review of low-risk research. However, the draft policy is unclear in what may qualify for delegated review. It appears that it is the intent that an initial protocol may qualify for delegated review if it only contains work identified as eligible for delegated review under Section IV-3. Clarified wording is recommended “for minor amendments to previously approved submissions or for initial research protocols”

There are inconsistencies between the descriptions of research that require committee review (Section IV-2) and research that may be eligible for delegated review (Section IV-3). A potential clarification is to state that “Where research is described by both Section IV-2 and Section IV-3, research meeting all applicable criteria specified in Section IV-3 may undergo delegated review unless another characteristic of the research independently requires review under Section IV-1 or IV-2. A delegated reviewer may refer any submission to the full IBC when warranted based on the risk assessment.”

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It is strongly recommended that NIH revise the approach to public posting of incidents so that detailed incident

reports are submitted to NIH but are not routinely required to be posted publicly in their entirety. Alternatively, NIH could provide a template for public posting of standardized, de-identified high level summary information of incidents that might include root-cause categories and corrective actions. NIH could separately require disclosure of additional information when a particular incident presents a compelling public health or safety interest.

This approach balances transparency objectives with the equally important need to preserve a just, non-punitive reporting culture in which researchers and staff are encouraged to report incidents, near misses, and potential safety concerns promptly and completely. It also provides protections for researchers that are increasingly threatened or harassed due to the tools or subject matter of their research.

Importantly, NIH would receive the information necessary to evaluate significant incidents, institutional responses, and compliance. The distinction would therefore be between information necessary for regulatory oversight and information necessary for public transparency, rather than assuming that the same level of detail is needed for both purposes.

6. Other feedback relevant to this resource: The timeline for institutional implementation and compliance with the revised policy should be at least a year after the publishing of the final rule instead of 6 months.

A six-month implementation period is insufficient given the breadth, complexity, and institutional impact. Revising electronic systems to accommodate the new regulations is a significant challenge that will likely prevent many institutions' ability to meet this timeline. Additionally, updating policies and procedures and ensuring that researchers have the training they need to understand the new requirements, including newly covered areas of research, will require additional time. The time required to identify newly covered research is one reason why it is critical for entities to be held to realistic and achievable implementation timelines.

NIH should provide a detailed description of the required elements of an institutional assurance and publish accompanying implementation guidance before policy adoption, including model assurance language, implementation templates, and sufficient lead time for institutions to develop. Administrative burden should be kept in mind in considering required elements.

344. Mary Kay Lobo

I am responding: On behalf of myself

Name: Mary Kay Lobo

Name of Organization: University of Maryland School of Medicine

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Molecular and behavioral neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: My laboratory uses hundreds of distinct adeno-associated viral (AAV) vectors to study how genes in specific brain cell types contribute to addiction and depression. These are engineered tools — they cannot replicate, they do not cause disease, and they are classified at the lowest biosafety level (BSL-1) by our institution. Every one of them has already been reviewed and approved by our Institutional Biosafety Committee (IBC). The draft policy would upend that entire body of approved work without providing any guidance on what happens next.

The draft says nothing about what happens to research that is already approved. Can we keep working under our current approvals? Do we have to resubmit everything from scratch? Can we amend existing protocols? Without clear answers, institutions will take the safest legal route: stop everything and resubmit. For a lab with hundreds of approved vectors, that could mean months of paperwork before a single experiment can move forward — for tools that pose no meaningful safety risk and have been in use for years.

The draft also lumps all viral vector research into a single broad category without the practical guidance that the current NIH Guidelines provide. The existing guidelines include specific, usable direction for common research tools like AAVs — what containment is required, how to assess risk, what paperwork is needed. The new policy removes all of that without replacing it. Investigators and biosafety committees will be left guessing, and different institutions will interpret the rules differently, creating a patchwork of inconsistent oversight across the country.

One additional gap: the draft provides no direction for laboratories like ours that are beginning to work with human stem cells (iPSCs) in combination with viral vectors. This is an increasingly common research approach, but the draft does not say how it should be classified or reviewed. Guidance on this combination needs to be developed and released before the policy takes effect.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The idea of tiered oversight, matching the level of review to the actual level of risk, is the right approach in principle. The

problem is that the draft does not define the tiers clearly enough to use them. Our AAVs are BSL-1 materials: the lowest risk category that exists. They cannot replicate, they do not cause disease in healthy people, and they have been used safely in research laboratories for decades. Yet under this draft, it is not clear that they would qualify for a lighter-touch review track. Without explicit criteria, our institution will default to full IBC review for everything, adding months of overhead for materials that pose no meaningful hazard.

The three-year renewal requirement is the single most damaging part of this draft for our lab. We have hundreds of approved AAV constructs. Every three years, we would need to resubmit them all — vectors that have not changed, that have been used safely year after year, that our IBC has already reviewed and approved. There is no safety justification for this. It is paperwork for the sake of paperwork, and it will consume enormous amounts of time from both researchers and biosafety staff that could be spent on actual science. NIH should allow institutions to use a "master protocol" approach, where a single protocol covers an entire class of well-characterized vectors, with individual new constructs added through a simple review process. Resubmitting hundreds of unchanged protocols every three years is not a safety measure.

What the draft also does not acknowledge is the real cost of all this compliance work. Tracking renewal deadlines for hundreds of constructs, preparing detailed incident reports within 24 hours, managing the public posting of meeting minutes, meeting new committee composition requirements — none of this happens for free. Most research labs do not have dedicated administrative staff for biosafety compliance. The practical result is that someone in the lab — a postdoc, a lab manager, the PI — will have to do it, taking time away from research. Or the lab will need to hire additional staff, which means spending grant money on administration instead of science. NIH has not estimated what this policy will cost the research community, and it should before moving forward.

The impact will be felt most by those who can least afford it. Junior faculty who are just starting their labs are building their research programs from scratch, generating new AAV constructs, and submitting initial protocols — all while on a tenure clock that stops for nothing. Unclear policy requirements and mandatory renewal cycles will slow them at the worst possible time. Graduate students and postdoctoral researchers are also directly harmed. NIH has invested heavily in fellowship and training programs specifically designed to help trainees complete their work on time. Administrative delays caused by this policy work directly against those investments.

There are also significant downstream complications that the draft does not address. Many research reagents, including plasmids and viral vectors, are obtained under Material Transfer Agreements (MTAs) that were negotiated under specific protocol conditions. When IBC protocols expire, are restructured, or are split across tiers, those MTAs may no longer cover the materials as they are now being used, requiring new rounds of negotiation with the originating institution before research can continue. This a predictable consequence of forcing protocol restructuring on materials whose biological properties have not changed.

One of the strengths of the current IBC system is that it maintains a continuous, evolving record of a laboratory's research within a single protocol. When a lab makes small changes — adding a new

construct, adjusting a payload, refining a method — those changes are tracked as modifications to an existing record. This makes audits, inspections, and reviews far more manageable, because the full history is in one place. The draft's push toward mandatory renewals and tiered restructuring would fragment that history across multiple records and time periods without providing any safety benefit. Biosafety oversight should be designed to make it easier to track what is happening in a lab, not harder.

Finally, IBC approvals do not exist in isolation. They are often directly linked to IACUC protocols and other institutional oversight systems that govern animal research. When an IBC protocol number changes, expires, or is restructured, that change can trigger required amendments across every linked IACUC protocol, even if nothing about the actual research has changed. For a lab with active animal studies and dozens of linked protocols, this could mean a wave of administrative amendments — submitted, reviewed, and approved — for procedures and animal welfare considerations that are completely unchanged. This kind of cascading compliance burden diverts time and institutional attention away from the oversight activities that actually matter.

3. Continued utility of Risk Groups: Risk Groups (RGs) were developed to describe how dangerous a naturally occurring pathogen is to a healthy person. They work reasonably well for that purpose, but they break down when applied to the engineered research tools we use. Our AAVs start from a naturally occurring virus, but that virus has been extensively modified — key genes that allow it to replicate have been removed entirely. What remains cannot reproduce, cannot spread, and cannot cause disease. Our institution classifies these vectors as BSL-1 specifically because of those modifications. But if risk classification starts from the parental virus's RG category, none of that transformation is captured. We would be assessed against the natural virus, not the tool we actually use.

Biosafety Levels (BSLs) are a better fit for this kind of work because they describe what safety practices are actually required in the lab. This is what matters for day-to-day research. Our AAVs are classified BSL-1, meaning they require standard lab practices and no special containment. That classification reflects the actual risk of working with these materials. We strongly recommend that BSL serve as the primary framework for classifying genetically modified research tools, with RG used only as a starting point when the research involves or is closely related to the natural, unmodified version of an agent. If RG is kept as the primary system, the policy must spell out exactly how classifications are adjusted for genetic modification — because right now, different institutions are making those adjustments differently, leading to inconsistent and sometimes arbitrary differences in what is allowed and under what conditions.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Encouraging biosafety practices beyond NIH-funded institutions makes sense. But the draft does not give non-NIH institutions a realistic path to get there. The main obstacle for most of these institutions is not willingness but capacity. Many do not have a full-time biosafety officer, an established safety committee, or staff with experience reviewing viral vector research. Asking them to voluntarily adopt a complex new framework without providing model templates, training resources, or step-by-step guidance is not a strategy that will work. Voluntary compliance provisions need to be paired with real tools that make compliance achievable for smaller or less-resourced institutions.

The draft also misses an important opportunity to reduce unnecessary duplication. Some non-NIH institutions are already operating under rigorous federal safety oversight through the CDC, USDA, FDA, or Department of Defense. They are not operating without safeguards; they are operating under different but comparably strict ones. Rather than requiring these institutions to build a parallel compliance structure just to meet NIH's framework, the policy should formally recognize equivalent oversight programs. Redundant bureaucracy does not improve safety it just creates more work.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting template requires a report within 24 hours for any "serious" incident, but the template never defines what "serious" means for research using BSL-1 viral vectors. A needlestick during an AAV injection is not the same as an exposure to a dangerous pathogen, but the draft treats them as if the same reporting process applies. Without a clear, practical definition — one that accounts for what the actual material is and what real risk it poses — labs and biosafety offices will not know how to apply this requirement consistently. Some will report everything out of caution; others will under-report. Neither is the right outcome. The template needs to include plain-language guidance that helps labs determine whether a given event actually requires a 24-hour report.

The public posting requirement for IBC meeting minutes raises a serious problem that the template does not address at all. IBC minutes describe ongoing research — often in detail, often before that research has been published or patented. Posting five years of unredacted minutes publicly would expose unpublished findings, novel research tools, and investigator-specific information. The template must specify what can and cannot be redacted before posting, and institutions need clear legal authority to make those redactions. Without that, the requirement will either discourage candid discussion in IBC meetings or result in researchers' unpublished work becoming public. The template also needs to allow batch review entries for labs with many similar constructs — requiring a separate detailed entry for each of hundreds of nearly identical AAV vectors would make meeting minutes unmanageably long.

6. Other feedback relevant to this resource: The most direct thing I can say about this draft is that it cannot be put into practice as written. Too many of the questions that labs and biosafety committees need answered are left for "future guidance." However, the six-month implementation clock starts when the policy is finalized, not when the guidance is ready. That means institutions will be expected to comply with a policy they cannot yet fully interpret. The result will be inconsistency, confusion, and for many labs a research pause while they wait for clarity.

There is no set effective date until the supporting guidance is finalized and publicly available. Six months is not enough time to restructure compliance systems when the practical meaning of the policy is still being worked out. The effective date should follow the guidance, not precede it.

AAV-specific guidance should be released on the same day the final policy goes live. The current NIH Guidelines include detailed, practical information about how to handle common research vectors like AAVs — what containment is required, how to assess risk, what a protocol should include. The new policy removes all of that. If it is not replaced before the policy takes effect, labs and biosafety committees will have less usable guidance than they do today. That is not an acceptable outcome. Clear written examples that provide direction for labs with existing IBC approvals will be necessary. Are current approvals still valid? Do we have to resubmit? Can we amend existing protocols? Without explicit

answers to these basic questions, institutions will require full resubmission of everything to be safe. For a lab with hundreds of approved AAV constructs, that is months of work — for research tools that have not changed and pose no new risk.

There is a need for transparency and honesty about what this policy will cost. Keeping up with renewal deadlines, writing 24-hour incident reports, managing public minute posting, and meeting new committee requirements all take real time and real money. Most labs do not have the staff to absorb this. Investigators will either redirect their own time from research to paperwork, or spend grant funding on additional administrative personnel. NIH has not estimated this cost or weighed it against the safety benefits. It should.

The impact on junior faculty and trainees should be addressed. A new faculty member building their lab from scratch, generating their first AAV constructs, and establishing their IBC protocols is in a fundamentally different position than an established lab. They have less staff, less institutional support, less margin for administrative delays and they are on a tenure clock that does not stop. This policy will slow them at the moment when momentum matters most. NIH also funds thousands of graduate students and postdocs through fellowships and training grants built on the assumption that trainees can complete their work on schedule. Paperwork-driven delays undermine that assumption directly. NIH should be required to assess the impact of this policy on trainee timelines and early-career productivity before it is finalized.

345. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Zoonotic Disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft describes safe, responsible and secure research, but is unclear in title consistency and whether the required program encompasses both biosafety and biosecurity. Please describe the program's full portfolio, including research safety, compliance, responsible conduct & ethical considerations, training, committee review & approval, and security where appropriate. It would be useful to provide an applicability table and consistent definitions for screening.

Our committee has commented widely and such comments need not be detailed again, with few exceptions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The draft requires an IBC, but should explicitly define appointment authority, institutional support, delegation and independent decision-making. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their required workload.

3. Continued utility of Risk Groups: Publish a standardized template distinguishing required, conditional, and optional fields.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): One item that was presented at our discussion, at least briefly, was that only IACUC and institutional IRB members receive stipends for attending meetings. Since Community members spend an equivalent amount of valuable time, travel, etc., it would seem appropriate and fair for them to be likewise compensated.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft links Assurances to public program records and requires public minutes and incident reports. But please consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary and security information.

6. Other feedback relevant to this resource: The proposed IBC Policy and Reporting Requirements are extensive and detailed in some ways and lacking in others. For example, it seems that our Committee repeatedly noted , or via some version thereof, that Institutions need timely, consistent decisions and coordination with related oversight systems.

346. Christine Johnson

I am responding: On behalf of myself

Name: Christine Johnson

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): infectious disease research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: please see attached

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Description: Comments on the Draft NIH Biosafety Policy

347. Doni Bloomfield and Tom Inglesby

I am responding: On behalf of myself

Name: Doni Bloomfield and Tom Inglesby

Name of Organization: Fordham Law School and Johns Hopkins University Center for Health Security

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosecurity, pandemic preparedness, law

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: a. The NIH should provide greater clarity about which experiments will be subject to central NIH review.

The draft Policy requires NIH review for "[r]esearch involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL," with some exceptions.

Unfortunately, the draft's definitions do not provide clear boundaries on which experiments would be subject to NIH review. The draft places in its scope "research involving . . . known or potential risk to human health" and, among other things, wild-type or genetically modified pathogens. The draft nowhere defines what constitutes a "potential risk to human health." The draft defines a novel agent or organism broadly as "[a]n agent or organism not existing in nature, deliberately designed, and possibly derived from multiple, different natural or synthetic sources (e.g., chimeras, or organisms generated by synthetic biology in conjunction with artificial intelligence)."

Under these definitions, many experiments that seem amenable to IBC review may be channeled into NIH review of uncertain duration. For example, consider a proposed experiment to use an RG2 agent, such as an adenovirus, that will be modified to make it less transmissible or otherwise less dangerous, in BSL-2 conditions. Although unlikely, the agent may pose a "potential risk to humans," and it certainly involves a modified pathogen. The resulting virus will likely constitute a "novel agent" because it was deliberately designed and does not exist in nature. It is unclear if the resulting agent has an RG classification or BMBL category because it is no longer an unmodified adenovirus. All of this would suggest that NIH review is called for under the draft Policy before the experiment can begin. At the same time, the specifics of the experimental set-up suggest that IBC review should be sufficient.

The NIH should address this ambiguity by clarifying: experiments involving agents that, in their unmodified form, already have a risk group designation should be classified in that risk group for purposes of the Policy even after modification, unless the experiment is reasonably anticipated to

increase the agent's transmissibility, virulence, or immune evasion.

b. The NIH should include oversight of high-risk animal and plant experimental work in NIH-funded institutions

While the Animal and Plant Health Inspection Service (APHIS), an agency within the U.S. Department of Agriculture (USDA), has primary federal responsibility for overseeing and managing the risks associated with animal and plant pathogen laboratory work, if the NIH is funding work in these fields—or if such work is taking place in NIH-funded institutions—it should provide oversight of this work. Its principal focus on this work should be to assess whether proposed work will increase an animal or plant pathogen's capability for transmission, its potential lethality, and/or its capacity to avoid the immune response of its animal or plant host. The greatest potential risk would be the potential for a novel modified pathogen to cause an epizootic or epiphytotic, or even a panzootic or panphytotic event.

c. The NIH should provide greater oversight of experiments involving genetically modified RG1 agents that pose material risks

Under the current Guidelines, any proposed experiment for introducing drug resistance to an agent in a manner that "could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture" requires NIH Director approval. The draft Policy, by contrast, specifies that all genetic modifications to RG1 agents require only IBC or sub-IBC review. The NIH should clarify that proposals to modify RG1 agents in a manner that is reasonably anticipated to materially increase the agent's transmissibility between humans, its virulence among humans or non-human animals or plants, or its ability to evade the immune system in eukaryotes should be subject to NIH review.

d. The NIH should clarify the definition of "novel agent or organism."

The draft Policy defines a novel agent or organism as "[a]n agent or organism not existing in nature, deliberately designed, and possibly derived from multiple, different natural or synthetic sources (e.g., chimeras, or organisms generated by synthetic biology in conjunction with artificial intelligence)." Because it is impossible to rule out an agent or organism existing in nature, we believe that a novel agent would be better defined as "[a]n agent or organism not known to exist in nature…"

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: a. The NIH Should Reconfigure the Risk Groups to Focus on Epidemic and Pandemic Risk Rather Than Individual Threat

The draft Policy does not say whether it plans to continue using the risk-group classification system included in the current Guidelines. We urge the NIH to revise the risk-group classification system to better focus on epidemic and pandemic risk, specifically by classifying agents that are highly transmissible, and to which most people are immune naïve, at RG3 or RG4. At present, the Guidelines categorize agents based on their "relative pathogenicity for healthy adult humans," rather than their risk to society. To take one example: The Guidelines allow scientists to handle resurrected 1918 influenza, which killed tens of millions of people when it first arose, in BSL-3 enhanced containment. But scientists

studying certain tick-borne viruses, which are deadly but very unlikely to spread between humans, must do so in BSL-4 conditions. Likewise, H2N2 influenza—which killed more than a million people worldwide in a pandemic in 1957–1958—can be studied in BSL-3 enhanced containment. Though the draft Policy does not provide its RG ranking, it appears to contemplate continuing this policy.

The most catastrophic risk of a lab accident or intentional pathogen release is the risk of sparking a major epidemic or a pandemic. A pathogen's virulence is only one factor to be considered in evaluating the appropriate biosafety procedures for its study. The NIH should reconfigure its RG system to consider transmissibility and societal immunity as key factors in RG ranking alongside virulence.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: a. The NIH Should Develop Guidance to Prevent the Creation of Key Mirror-Life Precursors

The creation of mirror bacteria could pose catastrophic risks to humanity and to the environment because such bacteria may be capable of evading most of life's existing defenses. The recent U.S. Government Policy for Stopping High-Risk Life Sciences Research bars the U.S. government from directly supporting the creation of mirror organisms. Yet the draft Policy does not mention mirror organisms or research into mirror biology. To be sure, any research proposing to create a mirror bacterium would presumably require NIH and IBC approval as an experiment involving a "novel agent" without preexisting categorization. But a great deal of the science behind creating mirror life—that is, science that enables others to create a mirror bacterium—might take place without itself creating a full mirror bacterium. Such endeavors may not fall within the draft Policy's definition of research subject to NIH or IBC review. We therefore urge the NIH to develop guidance to ensure that mirror-life precursor research is properly subject to NIH and/or IBC review, without unduly hampering useful research that does not study atypical chirality. The NIH may not be able to develop such guidance in time for the release of this version of this Biosafety Policy, but it should urgently pursue such guidance for subsequent updates, and should publicly signal in the finalized version of this Policy that it plans to urgently create such guidance.

b. The NIH Should Consider Issuing Guidance to Ensure that Biological AI Tools Created at NIH-Funded Institutions are Trained and Released Responsibly

The draft Policy recognizes, albeit with no detail, that agents created with the assistance of biologically trained AI models may pose serious risks. We agree that rapid advances in the capabilities of biological AI models—such as those that can design proteins or even entire viral genomes—are likely to bring both substantial benefits and risks. While the NIH does not have regulatory authority to require risk/benefit assessment and mitigation of all proposed biological AI models, it could precondition funding of biological AI models on such risk assessments. To establish an early test of this process, NIH should require PI-led risk/benefit reviews of proposed biological AI models that are reasonably anticipated to provide instructions, know-how, or blueprints for creating more transmissible, virulent, or immune-evasive organisms capable of infecting eukaryotes. Those reviews should be shared with NIH before funding decisions are made.

We also recommend that the NIH continue to study how it can create oversight mechanisms to require independent review of such AI models once produced, including mechanisms that draw on the policy precedent of the NIH Guidelines and IBCs.

Uploaded File: Bloomfield-Inglesby-Biosafety-Policy-RFI-Response.pdf

Description: Comments from Doni Bloomfield, Fordham Law School, and Tom Inglesby, Johns Hopkins University Center for Health Security

FORDHAM UNIVERSITY
THE SCHOOL OF LAW FACULTY

DONI BLOOMFIELD
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Response to NIH's RFI on the NIH's Draft Biosafety Policy
Submitted by the following authors in their individual capacities

Doni Bloomfield (Fordham University School of Law) and Tom Inglesby (Johns Hopkins University Center for Health Security)

We thank the NIH for the opportunity to comment on its draft Biosafety Policy. We believe that the draft, if implemented, would represent an improvement on the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules in several important respects. We also believe that the present draft can be improved along several dimensions. In these comments, we focus specifically on important ambiguities in the draft that may create undue burdens on researchers, areas to improve the clarity of the draft to ensure risky research receives adequate oversight, and arenas for the NIH to develop in follow-on supplements to address future risk from mirror life and AI models trained on biology.

Before we turn to areas for improvement, we wish to highlight several elements of the draft Policy that represent important advancements over the Guidelines.

First, we commend the NIH for moving past the Guidelines' historical focus on experiments involving recombinant or synthetic nucleic acids. As the draft Policy recognizes, wild-type pathogens, as well as pathogens that have been modified through passaging or techniques other than recombinant or synthetic approaches, can also pose substantial risks to society. The draft Policy will likely reduce these risks through improved oversight.

Second, the draft Policy appropriately provides an opening for no-fault, near-miss reporting to the National Biosafety Data and Safety Analysis Center. The NIH must ensure that it lives up to its promise not to punish or penalize reporting individuals or institutions that report near misses. Promoting a culture of reporting close calls, and addressing biosafety and biosecurity issues early, are essential to avoiding consequential lab accidents.

Third, the draft Policy's focus on increased scrutiny for experiments involving novel, emerging, and zoonotic agents is appropriate, especially in light of modern advances in biological AI tools.

We see room for further improvement as the NIH refines the draft. In what follows, we address three of the questions the agency sought comment on.

1. **<u>Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.</u>**

   a. **The NIH should provide greater clarity about which experiments will be subject to central NIH review.**

The draft Policy requires NIH review for "[r]esearch involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL," with some exceptions.[1]

Unfortunately, the draft's definitions do not provide clear boundaries on which experiments would be subject to NIH review. The draft places in its scope "research involving . . . known or potential risk to human health" and, among other things, wild-type or genetically modified pathogens. The draft nowhere defines what constitutes a "potential risk to human health." The draft defines a novel agent or organism broadly as "[a]n agent or organism not existing in nature, deliberately designed, and possibly derived from multiple, different natural or synthetic sources (e.g., chimeras, or organisms generated by synthetic biology in conjunction with artificial intelligence)."[2]

Under these definitions, many experiments that seem amenable to IBC review may be channeled into NIH review of uncertain duration. For example, consider a proposed experiment to use an RG2 agent, such as an adenovirus, that will be modified to make it less transmissible or otherwise less dangerous, in BSL-2 conditions. Although unlikely, the agent may pose a "potential risk to humans," and it certainly involves a modified pathogen. The resulting virus will likely constitute a "novel agent" because it was deliberately designed and does not exist in nature. It is unclear if the resulting agent has an RG classification or BMBL category because it is no longer an unmodified adenovirus. All of this would suggest that NIH review is called for under the draft Policy before the experiment can begin. At the same time, the specifics of the experimental set-up suggest that IBC review should be sufficient.

The NIH should address this ambiguity by clarifying: experiments involving agents that, in their unmodified form, already have a risk group designation should be classified in that risk group for purposes of the Policy even after modification, unless the experiment is reasonably anticipated to increase the agent's transmissibility, virulence, or immune evasion.

   b. **The NIH should include oversight of high-risk animal and plant experimental work in NIH-funded institutions**

While the Animal and Plant Health Inspection Service (APHIS), an agency within the U.S. Department of Agriculture (USDA), has primary federal responsibility for overseeing and managing the risks associated with animal and plant pathogen laboratory work, if the NIH is funding work in these fields—or if such work is taking place in NIH-funded institutions—it should provide oversight of this work. Its principal focus on this work should be to assess whether

[1] Draft Policy § IV-1. The Policy notes that experiments involving genetically modified versions of risk-group (RG) 1 agents may proceed after IBC or IBC-delegated review. See id. § IV-3.
[2] Id. § II.

proposed work will increase an animal or plant pathogen's capability for transmission, its potential lethality, and/or its capacity to avoid the immune response of its animal or plant host. The greatest potential risk would be the potential for a novel modified pathogen to cause an epizootic or epiphytotic, or even a panzootic or panphytotic event.

c. The NIH should provide greater oversight of experiments involving genetically modified RG1 agents that pose material risks

Under the current Guidelines, any proposed experiment for introducing drug resistance to an agent in a manner that "could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture" requires NIH Director approval.[3] The draft Policy, by contrast, specifies that all genetic modifications to RG1 agents require only IBC or sub-IBC review.[4] The NIH should clarify that proposals to modify RG1 agents in a manner that is reasonably anticipated to materially increase the agent's transmissibility between humans, its virulence among humans or non-human animals or plants, or its ability to evade the immune system in eukaryotes should be subject to NIH review.[5]

d. The NIH should clarify the definition of "novel agent or organism."

The draft Policy defines a novel agent or organism as "[a]n agent or organism not existing in nature, deliberately designed, and possibly derived from multiple, different natural or synthetic sources (e.g., chimeras, or organisms generated by synthetic biology in conjunction with artificial intelligence)." Because it is impossible to rule out an agent or organism existing in nature, we believe that a novel agent would be better defined as "[a]n agent or organism not **known to exist** in nature…"

2. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

a. The NIH Should Reconfigure the Risk Groups to Focus on Epidemic and Pandemic Risk Rather Than Individual Threat

The draft Policy does not say whether it plans to continue using the risk-group classification system included in the current Guidelines. We urge the NIH to revise the risk-group classification system to better focus on epidemic and pandemic risk, specifically by classifying agents that are highly transmissible, and to which most people are immune naïve, at RG3 or RG4. At present, the Guidelines categorize agents based on their "relative pathogenicity for healthy adult humans," rather than their risk to society.[6] To take one example: The Guidelines allow scientists to handle

[3] See 2024 Guidelines § III-A-1.
[4] Draft Policy § IV-3.
[5] We recognize that such experiments are likely to be barred by the recent U.S. Government Policy for Stopping High-Risk Life Sciences Research. Nonetheless, we believe that it is worth avoiding creating an unintentional carveout in the policy for research involving modified RG1 agents that may pose substantial risks.
[6] See 2024 Guidelines Appendix B, tbl. 1.

resurrected 1918 influenza, which killed tens of millions of people when it first arose, in BSL-3 enhanced containment. But scientists studying certain tick-borne viruses, which are deadly but very unlikely to spread between humans, must do so in BSL-4 conditions. Likewise, H2N2 influenza—which killed more than a million people worldwide in a pandemic in 1957–1958—can be studied in BSL-3 enhanced containment. Though the draft Policy does not provide its RG ranking, it appears to contemplate continuing this policy.[7]

The most catastrophic risk of a lab accident or intentional pathogen release is the risk of sparking a major epidemic or a pandemic. A pathogen's virulence is only one factor to be considered in evaluating the appropriate biosafety procedures for its study. The NIH should reconfigure its RG system to consider transmissibility and societal immunity as key factors in RG ranking alongside virulence.

3. **Feedback on the implementation resources and areas in which additional guidance would be beneficial.**

a. The NIH Should Develop Guidance to Prevent the Creation of Key Mirror-Life Precursors

The creation of mirror bacteria could pose catastrophic risks to humanity and to the environment because such bacteria may be capable of evading most of life's existing defenses.[8] The recent U.S. Government Policy for Stopping High-Risk Life Sciences Research bars the U.S. government from directly supporting the creation of mirror organisms.[9] Yet the draft Policy does not mention mirror organisms or research into mirror biology. To be sure, any research proposing to create a mirror bacterium would presumably require NIH and IBC approval as an experiment involving a "novel agent" without preexisting categorization.[10] But a great deal of the science behind creating mirror life—that is, science that enables others to create a mirror bacterium—might take place without itself creating a full mirror bacterium.[11] Such endeavors may not fall within the draft Policy's definition of research subject to NIH or IBC review. We therefore urge the NIH to develop guidance to ensure that mirror-life precursor research is properly subject to NIH and/or IBC review, without unduly hampering useful research that does not study atypical chirality. The NIH may not be able to develop such guidance in time for the release of this version of this Biosafety Policy, but it should urgently pursue such guidance for subsequent updates, and should publicly signal in the finalized version of this Policy that it plans to urgently create such guidance.

[7] See draft Policy, Introduction ("NIH intends to provide additional supplemental materials for the community through implementation resources . . . [including] training for research with RG3 influenza viruses.").
[8] See Katarzyna Adamala et al., Confronting Risks of Mirror Life, 386 Science 1351 (2024).
[9] See U.S. Government Policy for Stopping High-Risk Life Sciences Research, at tbl. 1 n. 3.
[10] Draft Policy § IV-1.
[11] See, e.g., Sana Zakaria et al., *Mirror Biology Research: Implications for Operational Governance* (RAND Corp., Doc. No. PE-A4952-1, 2026), https://www.rand.org/pubs/perspectives/PEA4952-1.html.

b. The NIH Should Consider Issuing Guidance to Ensure that Biological AI Tools Created at NIH-Funded Institutions are Trained and Released Responsibly

The draft Policy recognizes, albeit with no detail, that agents created with the assistance of biologically trained AI models may pose serious risks.[12] We agree that rapid advances in the capabilities of biological AI models—such as those that can design proteins or even entire viral genomes—are likely to bring both substantial benefits and risks. While the NIH does not have regulatory authority to require risk/benefit assessment and mitigation of all proposed biological AI models, it could precondition funding of biological AI models on such risk assessments. To establish an early test of this process, NIH should require PI-led risk/benefit reviews of proposed biological AI models that are reasonably anticipated to provide instructions, know-how, or blueprints for creating more transmissible, virulent, or immune-evasive organisms capable of infecting eukaryotes.[13] Those reviews should be shared with NIH before funding decisions are made.

We also recommend that the NIH continue to study how it can create oversight mechanisms to require independent review of such AI models once produced, including mechanisms that draw on the policy precedent of the NIH Guidelines and IBCs.[14]

[12] The draft Policy's definition of a "novel agent" references the possibility that such an agent could be designed with AI assistance.

[13] See Mortiz S. Hanke et al., *Dual-Use Artificial Intelligence and Biology: Upstream Risk-Benefit Reviews*, 17 Frontiers in Microbiology 1 (2026).

[14] See Jaspreet Pannu et al, *Dual-Use Capabilities of Concern of Biological AI Models*, 21 PLOS Comp. Bio. e1012975 (2025); Doni Bloomfield et al., *AI and Biosecurity: The Need for Governance*, 385 Science 831 (2024).

348. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Scope of Research
Please clarify the work under Section IV-3. Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members, specifically the definition of transgenic organisms at BSL-1/ABSL-1.
We ask that the following be considered exempt from review by the IBC, as was proposed during the listening sessions:
• Research conducted with transgenic organisms at BSL-1/ABSL-1.
• Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes.
• Research with well-characterized cell lines.

Increased administrative burden
Please clarify in the policy or in implementation guidance to what extent the Principal Investigator must document adequate biosafety training for the research they will be conducting.
We suggest defining “periodically” within the policy as a time point established by the institutional IBC.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We suggest that the project description requirement in the IBC minutes to be very high-level, so that institutions are not required to reveal information that would allow the substance of a not-yet-published research project to be made available to the public. This would allow institutions to protect proprietary information of the research and the autonomy of the review process.

We suggest that the implementation guidance provide examples of incidents that are reportable to the NIH and non-reportable incidents that only require IBC review.
We ask the NIH to reconsider the requirement of publicly posting incident reports. We have concern that this requirement may lead to underreporting due to perceptions of the punitive nature of publicly displaying identifiable information and fear. If there is no change in the policy, we suggest that the name of the PI and NIH grant or contract number be removed from the public-facing website. As the responsibility of the National Biosafety Data and Safety Analysis Center is to independently aggregate, de-identify, and analyze laboratory biosafety incident data, near-misses and anomalies, trends in laboratory incidents would be available through this center, without publicly posting incident reports.

6. Other feedback relevant to this resource: We recommend moving the Risk Group categorization of agents from a published document to a live document so that the rapid pace of changes in risk group categorizations can provide the most value to biosafety professionals.

349. Ramesh Chandra

I am responding: On behalf of myself

Name: Ramesh Chandra

Name of Organization: University of Maryland, Baltimore

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): https://www.medschool.umaryland.edu/profiles/chandra-ramesh/

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: As Director of a university Viral Vector Core, I am concerned that the broader scope of this policy could add considerable paperwork to work already covered by institutional biosafety review. My staff and the investigators we serve would both spend more time preparing and updating documents.
The policy needs to clearly identify which activities are covered, which are outside its scope, and what documentation is actually necessary. This is especially important for routine AAV and lentiviral work and experiments using established cell lines.
Unclear requirements could lead to overlapping submissions and repeated requests for the same information. For a core facility, that additional work has a cost. It could reduce the time available for vector production and consultation, while researchers wait longer for materials and approvals.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): As Director of a university Viral Vector Core, I am concerned about the time and cost of requiring a completely new application every three years for unchanged, previously approved research. Core staff and investigators would spend time rewriting information that the IBC has already reviewed.

An important strength of maintaining one updated protocol is that it keeps the history of the work together. Related vectors, reagents, amendments, and safety decisions can be followed in one record. This helps investigators and biosafety staff prepare for reviews, audits, and inspections. If renewal or assignment to different review categories requires replacing or splitting these records, that history could become harder to follow without improving safety.

Our core produces vectors for multiple research groups. Repeated documentation on our side, followed by similar submissions from each investigator, could create substantial duplicate work. We may need additional administrative staff and could have to increase service fees to cover those costs. Researchers would then face both higher charges and more paperwork.

Please allow shorter renewals for unchanged, lower-risk work and shared protocols for related

constructs. Preserve the complete approval history and focus additional review on changes that affect the biosafety assessment.

3. Continued utility of Risk Groups: For the work we do, the safety assessment needs to consider the actual vector, what it carries, and how it is produced and used. A broad classification alone does not answer those questions.
My concern is that unclear guidance could result in extensive new documentation for closely related vectors, even when the relevant risks are already understood. Core staff would have to prepare these assessments, and investigators could face additional questions and delays before beginning their experiments.
Please provide clear examples for common AAV and lentiviral applications. Allow us to reference previously reviewed information and document what has changed, rather than repeat the entire assessment for every related construct. This would let researchers and biosafety staff concentrate on differences that matter.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): A process that requires extensive paperwork, recurring submissions, and substantial staff time is unlikely to encourage voluntary participation. Smaller organizations may not have someone available to manage these responsibilities.
From my perspective as a scientist and core director, access to practical help would be more useful than additional administrative requirements. Free training, straightforward forms, and affordable access to biosafety review would make participation more realistic.
NIH should clearly distinguish required activities from voluntary recommendations. Organizations should be able to use suitable existing records and procedures rather than create a second administrative system. Otherwise, the cost and workload could discourage the participation NIH is trying to encourage.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: My concern with additional reporting templates is that the same event could require several versions of the same information. Core staff and investigators could spend considerable time preparing laboratory records, institutional reports, NIH reports, and material for public posting.
The templates should allow information already recorded in institutional systems to be reused. Instructions must clearly explain which incidents require NIH notification and which are handled locally. Staff should not have to spend hours determining which reporting process applies.
Meeting minutes should record the safety discussion and decision without repeating the research application. NIH should also provide clear instructions for preparing public versions. Reviewing and removing personal or confidential information takes staff time and needs to be included when estimating the workload.

6. Other feedback relevant to this resource: The additional administrative work would fall on staff who already produce vectors, assist investigators, and manage existing requirements. NIH should assess the staffing and costs involved before implementation and consider financial support for this work.

Guidance should explain how existing protocols, amendments, reagent inventories, and approval histories will be carried forward. Laboratories should not have to reconstruct years of documentation simply because a protocol receives a new number or moves to a different review category. Linked records and reusable information would help preserve continuity.

I am also concerned about materials covered by Material Transfer Agreements. NIH should clarify how these materials will be handled during protocol renewal or migration. A change in protocol status should not lead to unnecessary repeat approvals or material-transfer paperwork when the material, permitted use, and safety risks remain unchanged.

Please provide sample renewal forms, shared-protocol examples, and clear instructions for documenting these transitions. A reasonable transition period is needed so that administrative changes do not interrupt vector production or researchers' access to previously approved materials.

350. University of Otago

I am responding: On behalf of an organization

Name: Charlotte Wilson

Name of Organization: University of Otago

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We support the objective of proportionate, risk-based oversight of research involving biohazards. However, we have significant concerns about applying the Policy to non-NIH-funded research solely because it is undertaken at an institution that receives NIH funding.
New Zealand institutions already operate under established, compulsory and comprehensive national legislation for biological hazards. Extending NIH requirements to research that receives no NIH support would duplicate existing oversight and create significant administrative costs without necessarily providing a corresponding reduction in risk.
We recommend allowing non-US institutions to demonstrate that comparable national regulatory and institutional oversight is already in place. This would also be consistent with the NIH's existing approach - we recommend that the final Policy retain the host-country provision in Section I-C-1-b-(3). Under this approach, a foreign institution would attest in its Biosafety Assurance that research not supported by NIH is overseen under host-country law, using safety practices reasonably consistent with the Policy. It would identify the relevant national regulators, and NIH would retain the right to request information.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): We support tiered, risk-based oversight and recommend that NIH explicitly recognise regulatory systems outside the United States that provide oversight consistent with the Policy.
In New Zealand, biological risks are managed through established primary legislation including the Biosecurity Act 1993, Hazardous Substances and New Organisms Act 1996, and the Health and Safety at Work Act 2015. Genetically modified and other new organisms are subject to approval and containment requirements administered through the Environmental Protection Authority (EPA). Containment facilities are approved by the Ministry for Primary Industries (MPI), and Institutional Biological Safety Committees approve low-risk genetic modification under authority delegated by the Environmental Protection Authority.
Some elements of these frameworks are expressed differently from the draft Policy. New Zealand specifies containment as PC1–PC4 (under AS/NZS 2243.3 and the MPI/EPA containment standard) rather than BSL/ABSL, and we ask that NIH recognise equivalent international containment classifications. Definitions also differ: the draft Policy's definition of genetic modification includes stable alterations

introduced by passaging, chemical or radiological means, which New Zealand law generally does not treat as genetic modification. Requiring element-by-element alignment with the Policy would be impractical, even where overall standards of oversight are consistent.
We would therefore welcome an approach in which NIH requirements supplement existing national arrangements where an identifiable gap exists, rather than establishing a parallel oversight system.

3. Continued utility of Risk Groups: We support retaining Risk Groups as a baseline for risk assessment rather than using Biosafety Level as the primary measure of risk.
Risk Group and Biosafety Level serve different purposes. Risk Group informs assessment of the organism's inherent hazards, while the appropriate containment level should result from an activity-specific risk assessment considering factors such as experimental procedures, scale, exposure routes and genetic modifications.
This distinction is particularly important for genetically modified organisms, where modification may increase, decrease or leave unchanged the risk presented by the parental organism.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH guidance and resources may provide useful examples of good biosafety practice for research outside the Policy's scope. The University would welcome the opportunity to draw on NIH guidance where it adds value to existing practice. Nevertheless, we recommend that non-NIH-funded research at foreign institutions should be voluntary only, sitting alongside national oversight, rather than as a condition of an institution receiving NIH funding.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We support transparency in biosafety oversight, appropriate documentation and incident reporting. New Zealand universities are already subject to the Official Information Act 1982, which provides public access to institutional information. However, public posting of IBC minutes and incident reports raises concerns regarding privacy, staff safety, confidentiality, commercially sensitive information and intellectual property, particularly for institutions operating under non-US legislation such as New Zealand's Privacy Act 2020.
We ask that NIH specify the minimum information required, how information will be protected and whether it may be publicly disclosed. Foreign institutions should be able to redact or withhold information where disclosure would conflict with national law or legitimate privacy, commercial, intellectual property or security obligations.

6. Other feedback relevant to this resource: Institution-wide application would have significant resourcing implications, including additional biosafety review, administration, training, record keeping and reporting for projects receiving no NIH support.
NIH currently supports 0.1% of active projects at the University. Institution-wide provision would extend NIH requirements to an overwhelming majority of projects that receive no NIH support.
These costs would fall on research that NIH does not fund, without a corresponding reduction in risk where national oversight already applies.
We recommend that NIH:
• limit mandatory requirements to research with defined NIH funding;
• recognise overseas regulatory and institutional oversight that is reasonably consistent with the Policy, as provided for in Section I-C-1-b-(3) of the current NIH Guidelines;
• minimise duplication of reporting already required by national regulators;

• provide specific implementation guidance for foreign institutions.
We thank NIH for the opportunity to comment and would welcome further engagement as the Policy is finalised.

Uploaded File: Otago_NIH_biosafety_response_FINAL.pdf

Name of Organisation: University of Otago

Type of Organsiation: Academic Institution

The University of Otago is a leading research-intensive university in New Zealand, and values its long-standing research partnership with NIH. We share NIH's goal of biosafety oversight that is transparent, adaptive, accountable and proportionate to risk. Our comments focus on how the Policy would apply to non-NIH-funded research at institutions outside the United States that already operate under robust national regulatory frameworks.

1. **Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.**

We support the objective of proportionate, risk-based oversight of research involving biohazards. However, we have significant concerns about applying the Policy to non-NIH-funded research solely because it is undertaken at an institution that receives NIH funding.

New Zealand institutions already operate under established, compulsory and comprehensive national legislation for biological hazards. Extending NIH requirements to research that receives no NIH support would duplicate existing oversight and create significant administrative costs without necessarily providing a corresponding reduction in risk.

We recommend allowing non-US institutions to demonstrate that comparable national regulatory and institutional oversight is already in place. This would also be consistent with the NIH's existing approach - we recommend that the final Policy retain the host-country provision in Section I-C-1-b-(3). Under this approach, a foreign institution would attest in its Biosafety Assurance that research not supported by NIH is overseen under host-country law, using safety practices reasonably consistent with the Policy. It would identify the relevant national regulators, and NIH would retain the right to request information.

2. **Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).**

We support tiered, risk-based oversight and recommend that NIH explicitly recognise regulatory systems outside the United States that provide oversight consistent with the Policy.

In New Zealand, biological risks are managed through established primary legislation including the Biosecurity Act 1993, Hazardous Substances and New Organisms Act 1996, and the Health and Safety at Work Act 2015. Genetically modified and other new organisms are subject to approval and containment requirements administered through the Environmental Protection Authority (EPA). Containment facilities are approved by the Ministry for Primary Industries (MPI), and Institutional Biological Safety Committees approve low-risk genetic modification under authority delegated by the Environmental Protection Authority.

Some elements of these frameworks are expressed differently from the draft Policy. New Zealand specifies containment as PC1–PC4 (under AS/NZS 2243.3 and the MPI/EPA containment standard) rather than BSL/ABSL, and we ask that NIH recognise equivalent international containment classifications. Definitions also differ: the draft Policy's definition of genetic modification includes stable alterations introduced by passaging, chemical or radiological means, which New Zealand law generally does not treat as genetic modification. Requiring element-by-element alignment with the Policy would be impractical, even where overall standards of oversight are consistent.

We would therefore welcome an approach in which NIH requirements supplement existing national arrangements where an identifiable gap exists, rather than establishing a parallel oversight system.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

We support retaining Risk Groups as a baseline for risk assessment rather than using Biosafety Level as the primary measure of risk.

Risk Group and Biosafety Level serve different purposes. Risk Group informs assessment of the organism's inherent hazards, while the appropriate containment level should result from an activity-specific risk assessment considering factors such as experimental procedures, scale, exposure routes and genetic modifications.

This distinction is particularly important for genetically modified organisms, where modification may increase, decrease or leave unchanged the risk presented by the parental organism.

4. **Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).**

NIH guidance and resources may provide useful examples of good biosafety practice for research outside the Policy's scope. The University would welcome the opportunity to draw on NIH guidance where it adds value to existing practice. Nevertheless, we recommend that non-NIH-funded research at foreign institutions should be voluntary only, sitting alongside national oversight, rather than as a condition of an institution receiving NIH funding.

5. **Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.**

We support transparency in biosafety oversight, appropriate documentation and incident reporting. New Zealand universities are already subject to the Official Information Act 1982, which provides public access to institutional information. However, public posting of IBC minutes and incident reports raises concerns regarding privacy, staff safety, confidentiality, commercially sensitive information and intellectual property, particularly for institutions operating under non-US legislation such as New Zealand's Privacy Act 2020.

We ask that NIH specify the minimum information required, how information will be protected and whether it may be publicly disclosed. Foreign institutions should be able to redact or withhold information where disclosure would conflict with national law or legitimate privacy, commercial, intellectual property or security obligations.

6. **Feedback on the implementation resources and areas in which additional guidance would be beneficial.**

Institution-wide application would have significant resourcing implications, including additional biosafety review, administration, training, record keeping and reporting for projects receiving no NIH support.

NIH currently supports 0.1% of active projects at the University. Institution-wide provision would extend NIH requirements to an overwhelming majority of projects that receive no NIH support.

These costs would fall on research that NIH does not fund, without a corresponding reduction in risk where national oversight already applies. We recommend that NIH:

- limit mandatory requirements to research with defined NIH funding;
- recognise overseas regulatory and institutional oversight that is reasonably consistent with the Policy, as provided for in Section I-C-1-b-(3) of the current NIH Guidelines;

- minimise duplication of reporting already required by national regulators;
- provide specific implementation guidance for foreign institutions.

We thank NIH for the opportunity to comment and would welcome further engagement as the Policy is finalised.

351. Max Baymiller

I am responding: On behalf of myself

Name: Max Baymiller

Name of Organization: Central Connecticut State University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): RNA Biology of Human Cells

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am writing to recommend the removal of language in the “Draft NIH Biosafety Policy for Research Involving Biohazards” (NOT-OD-26-112) which is incorrect and misleading, as it implies that treatments which do not change an organisms genetic information would. Specifically, a portion of the below excerpt:

"Genetic Modification:
The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
Have the potential for one or more cycles of replication in a cell; or
Can be transcribed or translated; or
The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means."

In the third bullet point: introduction of molecules which can be transcribed or translated does not constitute genetic modification. In usage of this term both by laypeople and expert biomedical researchers such as myself, genetic modification is restricted to manipulations which will change or add to the existing sequence of an organisms genetic material (DNA) in a lasting fashion. This does not include the inherently temporary introduction of messenger RNA molecules.

The draft must be amended to reflect that introduction of nucleic acids which do not persist long term in the cell does not constitute genetic modification.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): No comments at this time.

3. Continued utility of Risk Groups: No comments at this time.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No comments at this time.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: No comments at this time.

6. Other feedback relevant to this resource: No comments at this time.

352. Yale University

I am responding: On behalf of an organization

Name:

Name of Organization: Yale University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: FINAL-Comments-on-the-Draft-NIH-Biosafety-Policy-for-Research-Involving-Biohazards.pdf

Yale University
OFFICE OF THE PROVOST

Michael C. Crair
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October 17, 2026

Re: Draft NIH Biosafety Policy for Research Involving Biohazards, Notice Number NOT-OD-26-112

Dear NIH Office of Science Policy:

Yale University appreciates the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. Yale supports NIH's goal of modernizing federal biosafety oversight and creating a more comprehensive framework for research involving biological hazards. We also support the use of delegated review as a proportionate mechanism for lower-risk activities. However, several provisions of the draft would substantially expand institutional review, reporting, and public-disclosure obligations without sufficiently distinguishing activities that present meaningful biosafety risk from routine or historically exempt research. In their current form, these provisions could divert investigators, Biological Safety Officers, Institutional Biosafety Committees, and institutional resources away from higher-risk work while weakening the candid reporting culture on which effective biosafety programs depend.

Our principal recommendation is that NIH revise the final policy around a clear, risk-based framework. The policy should preserve well-established exemptions for minimal-risk research, align the level of review with the nature and magnitude of the hazard, avoid duplicating oversight already provided under other federal requirements, and permit institutions to concentrate their biosafety resources on activities that present credible risks to personnel, public health, or the environment.

1. Preserve a risk-based scope and established exemptions

The draft policy broadly includes genetically modified cells, viruses, and organisms; primary cells that may contain adventitious agents; plasmids; transgenic organisms; well-characterized cell lines; and biological toxins not on the Select Agent list. Without risk-based qualifiers or a dedicated exclusions section, this scope would bring large categories of routine, low-risk, and historically exempt research into Institutional Biosafety Committee (IBC) oversight. The result would be a substantial increase in registrations and delegated reviews even when the underlying activity has little or no plausible capacity to cause disease, toxicity, environmental harm, or loss of containment.

The current exemptions reflect decades of institutional experience with categories of research that have not presented significant risks to human health or the environment. Retaining those distinctions would allow IBCs to continue directing their attention to work with more consequential hazards while preserving institutional authority to review low-risk activities locally. NIH should revise or eliminate an established exemption only when scientific evidence or operational experience demonstrates that it no longer provides adequate protection. The final policy should also include a transparent process for adjusting exclusions as research practices and technologies change.

The final policy should expressly exclude, or otherwise remove from mandatory federal review, five categories that generally present minimal biosafety risk: genetically modified RG1 agents; transgenic organisms maintained at BSL-1 or ABSL-1; low-risk plasmids and replication-incompetent, non-integrating vectors expressing reporter or comparably low-risk transgenes; well-characterized cell lines; and non-Select Agent toxin proteins that do not meet an objective potency threshold. Institutions should remain free to review these activities locally when experiment-specific circumstances warrant additional oversight.

The plasmid category illustrates the practical scale of the proposed expansion. Yale laboratories routinely create and modify large numbers of plasmids as part of iterative experiments involving low-risk genes, and no reliable institution-wide inventory exists because constructs may change repeatedly within a single research program. Requiring each such construct or variation to enter an IBC or delegated-review process would impose substantial documentation and review effort without a corresponding increase in biosafety protection.

Yale therefore recommends that NIH add a dedicated exclusions section; retain the exemptions in Section III-F and Appendix C of the April 2024 NIH Guidelines unless an evidence-based rationale supports a change; preserve certified host-vector, tissue-culture, and qualifying transgenic-rodent exemptions; and permit institutions to determine whether otherwise excluded activities warrant local review. Federal reporting, assurance, public-minutes, and enforcement requirements should not attach solely because an institution voluntarily elects to review an excluded activity.

2. Retain essential risk-assessment guidance from the current NIH Guidelines

The draft policy replaces a detailed, longstanding framework with a shorter policy document but does not preserve several resources that institutions rely on to conduct consistent risk assessments. Appendix B's classification of etiologic agents by Risk Group remains a practical starting point for evaluating agents, particularly because the BMBL primarily uses biosafety levels rather than providing a comprehensive Risk Group classification. Other current provisions continue to provide valuable operational guidance including the experiment categories and exemptions in Section III, the natural-exchanger provisions in Appendix A, the Major Actions framework in Appendix D, the toxin framework in Appendix F, the physical and animal containment provisions in Appendices G and M, the large-scale provisions in Appendix K, and the plant-containment provisions in Appendix P.

Yale recommends that NIH retain these materials within the final policy or republish them as authoritative companion guidance. At a minimum, NIH should preserve Appendix B's Risk Group framework and the established toxin potency thresholds, and should ensure that institutions have a stable federal source for physical containment, animal containment, large-scale research, and other specialized risk assessments.

3. Refine the definition of genetic modification

The draft definition of genetic modification includes stable genomic alterations arising through passaging and through chemical or radiological means. As written, this language could encompass routine subculturing, the accumulation of undefined laboratory adaptations, and activities whose principal risks are chemical or radiological rather than biological. Researchers and IBCs may be unable to determine when ordinary passaging has produced a change covered by the policy, and IBCs generally are not the appropriate oversight body for hazards arising solely from chemical or radiological mutagens.

NIH should remove chemical and radiological means from the definition unless the resulting biological change itself creates a reasonably foreseeable increase in biosafety risk. Passaging should be limited to deliberate culturing under selective conditions that could reasonably be expected to increase virulence, pathogenicity, transmissibility, host range, tissue tropism, resistance, or another risk-relevant characteristic. Transient, nonintegrating materials that do not modify the genome should likewise remain outside the definition when they do not otherwise create a covered biological hazard.

4. Align review pathways with actual risk and existing oversight

Several review categories do not appear proportionate to the risks presented. Primary human cells and tissues of unknown infectious status are already addressed through the Occupational Safety and Health Administration Bloodborne Pathogens Standard and established institutional programs. Requiring full IBC review merely because an adventitious agent cannot be excluded would duplicate oversight and could place potentially contaminated material under a more stringent pathway than direct work with a known RG2 agent. Routine primary cells handled under universal precautions should be eligible for delegated review, with full committee review reserved for materials known or reasonably suspected to contain an RG3 or RG4 agent or for procedures likely to propagate, amplify, concentrate, or aerosolize such an agent.

The final policy should also state expressly that wild-type RG1 biological agents are outside its scope and should use that exclusion consistently across the scope, definitions, and review categories. Conversely, work with RG2 human pathogens warrants full IBC consideration rather than automatic delegated review because the relevant risk depends on the agent, procedures, quantities, routes of exposure, and available countermeasures. IBCs should retain authority to elevate any delegated matter when the institutional risk assessment warrants full committee review.

5. Remove the requirement to publicly post individual incident reports

Yale strongly supports timely reporting, investigation, and shared learning from biosafety incidents. We are concerned, however, that mandatory public posting of individual incident reports, including lower-risk incidents reviewed only by the institution, will undermine those goals. Even when the affected individual is not named, the combination of the Principal Investigator's name, research material, incident circumstances, personnel role, medical response, location, root cause, and corrective actions may permit identification of an individual, laboratory, or specialized research program. Public posting may therefore discourage prompt reporting of minor incidents, suspected exposures, and near misses, weakening the candid reporting culture that effective biosafety programs have worked to build.

Event-specific disclosure may also create research and institutional security concerns. Identifying a Principal Investigator and describing distinctive agents, animal models, containment practices, facility circumstances, or corrective measures could reveal sensitive information about research programs or security controls. Any transparency requirement should therefore be designed to avoid exposing details that could facilitate misuse, targeting, or disruption of personnel, laboratories, or institutional operations.

NIH should require applicable reports to be submitted to NIH and maintained institutionally, while using the National Biosafety Data and Safety Analysis Center to publish aggregated, deidentified analyses of recurring hazards, contributing factors, corrective actions, and national trends. Incidents requiring only institutional or IBC review should not be publicly posted. If NIH

retains a public-disclosure requirement, it should be limited to standardized summaries of confirmed significant incidents, should not identify the Principal Investigator or include combinations of details that could reasonably identify affected people or programs, and should permit delayed publication until investigations, occupational-health evaluations, corrective actions, and related processes are complete.

6. Establish clear thresholds for NIH incident notification

Immediate NIH notification should be limited to incidents presenting a credible and significant risk of infection, transmission, environmental release, or material loss of containment. The final policy should more precisely define the circumstances that constitute a suspected laboratory-acquired infection, a credible community risk or exposure, treatment beyond basic first aid, and a substantive compliance violation. Precautionary medical evaluation, diagnostic testing, vaccination, or prophylaxis should not independently make an event reportable when a meaningful exposure is not reasonably suspected. Likewise, equipment or facility failures should require federal notification only when containment is compromised or a credible risk is created. A component failure that is managed by functioning redundant systems should remain subject to institutional documentation and review.

The 24-hour period should begin when the BSO, IBC Chair, IBC office, institutional official, or another designated authority has sufficient information to reasonably determine that the event meets NIH criteria. NIH should distinguish immediate notification, routine reporting, and institution-only documentation, and should limit federally reportable compliance violations to substantive failures that materially compromise biosafety oversight or result in covered research being conducted without required approval or containment.

7. Clarify delegated review and public-minutes requirements

Delegated review can improve proportionality, but its value will be diminished if every approval must later be “reported in full” in publicly posted IBC minutes. The final policy should clarify that a structured summary or consent agenda satisfies this requirement. Such a summary could identify the institutional registration number, general research category, type of action, broad class of biological material, containment level, approval date, and material conditions without reproducing a protocol-level narrative or risk assessment. Purely administrative changes that do not affect the biosafety assessment should not require individual reporting in public minutes.

The policy should also permit ecological or environmental expertise required for review of gene drive modified organisms to be supplied by non-voting consultants or ad hoc experts. Requiring such specialists to serve as voting members when their expertise is needed only intermittently can create unnecessary quorum and attendance complications without improving the quality of review.

8. Use a risk-based renewal framework

A mandatory de novo review every three years would substantially increase workload for investigators, biosafety staff, IBC members, and institutional officials, including for research that has not materially changed.

NIH should permit approvals of up to five years, supported by annual investigator certification, prospective review of risk-relevant amendments, and authority for the IBC to shorten an approval period when warranted. Unchanged research should be eligible for streamlined renewal by a BSO or qualified IBC delegate after confirmation that the existing risk assessment, containment, and approval conditions remain appropriate. The policy should also permit

reasonable administrative extensions when a complete renewal has been submitted before expiration and institutional review remains in progress.

9. Apply objective thresholds to toxins and self-aggregating proteins

The draft's broad toxin definition could extend federal oversight to ordinary proteins and peptides that can cause harm only at high doses or under circumstances that do not present a meaningful laboratory biosafety risk. NIH should retain objective potency thresholds from the current Guidelines and distinguish review pathways according to potency, quantity, concentration, physical form, route of exposure, aerosol potential, and proposed manipulation. The final policy should also clarify that delegated review applies to non-Select Agent toxin proteins and peptides, not only to "biological toxin proteins."

IBC oversight of self-aggregating proteins should likewise depend on evidence of a credible biosafety hazard rather than aggregation alone. Classical mammalian prions should remain within IBC purview. Other protein assemblies should be assessed according to evidence of persistent self-propagating seeding, cellular or tissue spread, experimental transmissibility, resistance to decontamination, source and concentration, and the proposed routes of exposure. Routine work with monomeric proteins or aggregates lacking evidence of biological propagation should not automatically require full IBC review.

10. Clarify review of emerging, novel, and zoonotic agents

Section IV-1 should not require NIH review solely because an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum-containment recommendation in the BMBL. The BMBL is not an exhaustive inventory, and the absence of an entry does not itself establish elevated risk. Mandatory federal review should be limited to cases in which the absence of an established classification creates material uncertainty concerning appropriate containment or the potential for serious human, community, or environmental harm.

NIH should permit IBCs to make and document an institutional risk assessment using closely related agents, published evidence, and other authoritative information when adequate information is available. When federal review is required, institutions should be able to initiate work at a conservatively selected containment level unless NIH identifies a specific reason the work should not proceed. NIH should establish target review timelines and maintain a searchable repository of determinations that institutions may rely on for the same or materially equivalent agents, constructs, attenuations, and experimental activities.

11. Provide a realistic transition for ongoing research

Six months is not sufficient for institutions to revise policies, registrations, electronic systems, training, websites, reporting processes, and committee workflows while also reviewing a substantially expanded portfolio of ongoing research. Yale currently has more than 1,000 principal investigators using biological materials, more than 6,000 laboratories, approximately 710 active registrations involving recombinant or synthetic nucleic acid molecules, and more than 500 IACUC protocols, including over 400 involving mice. Many laboratories also maintain extensive collections of cell lines and plasmids that have accumulated over years of research. One long-established Yale laboratory alone maintains nearly 900 cell lines, approximately two-thirds of which are human. Requiring immediate re-registration and review of these previously approved or exempt activities would create a major administrative surge with limited safety benefit.

Yale recommends an implementation period of at least one year after publication of the final policy. Existing approvals should remain valid through their current expiration dates, and previously approved or institutionally reviewed activities should transition at their next scheduled renewal. NIH should publish final definitions, templates, reporting criteria, technical specifications, and implementation guidance before the transition period begins and should provide a corrective-action period before imposing enforcement for implementation-related deficiencies. NIH should also assess the personnel and financial burden of the final requirements, including the cumulative effect on investigators, IBCs, biosafety programs, animal-care programs, and institutional systems.

Because the draft would create new obligations across investigators, IBCs, biosafety offices, animal-care programs, information systems, and institutional administration, Yale also recommends an independent assessment by the U.S. Government Accountability Office of the personnel, financial, and operational consequences of the final framework. Such an analysis should evaluate both direct compliance costs and the opportunity cost of redirecting biosafety expertise from higher-risk research to routine or minimal-risk activities.

Before finalizing the policy, NIH should also provide additional time for consultation and extend the public-comment process. Further listening sessions would allow NIH to test whether the revised framework responds to the operational concerns raised by research institutions and to clarify how institutional discretion, exclusions, and delegated review will function in practice. Additional time would also enable professional organizations, including ABSA International and its affiliates, to collect broader data on investigator workload, staffing needs, implementation costs, and the likely effects on institutional reporting cultures.

Conclusion

Yale supports NIH’s effort to modernize and unify biosafety oversight. A successful final policy should strengthen the review of research presenting meaningful risk while preserving the flexibility, exemptions, and institutional judgment that have allowed IBCs to direct attention to the activities that most warrant scrutiny. Revising the draft to incorporate clear risk thresholds, retain established guidance, protect candid incident reporting, avoid duplicative oversight, and provide a workable transition will better advance the shared goals of safety, accountability, scientific progress, and public trust.

Sincerely,



Michael Crair
Vice Provost for Research, Office of the Provost
William Ziegler III Professor of Neuroscience

353. Alec Snelling

I am responding: On behalf of myself

Name: Alec Snelling

Name of Organization:

Type of Organization: Other

Role: Member of the Public

Date Submitted: 10/18/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

354. Karen Ottemann

I am responding: On behalf of myself

Name: Karen Ottemann

Name of Organization: UC Santa Cruz

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Re: Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)
To the NIH Office of Science Policy:
I am Researcher and Professor at UC Santa Cruz with over 25 years of experience in microbiology. Of course I appreciate the idea to modernize biosafety oversight and agree that the NIH Guidelines, written around recombinant DNA, need updating. My concerns below are meant to help the final policy achieve its safety goals without undermining them.
1. Scope and the definition of biohazards
Extending oversight beyond recombinant and synthetic nucleic acids to all biohazards is a major change. I am concerned that "known or potential risk to human health" is broad enough to sweep in large amounts of routine, low-risk work, such as well-characterized BSL-1 organisms and standard clinical or environmental samples. Without clear, objective criteria and explicit exemptions for such work, institutions will likely over-report and over-review to avoid noncompliance. That would bury researchers an IBCs in low-value submissions and pull attention from higher-risk research. I urge NIH to define the scope with concrete, testable thresholds and to publish worked examples of covered and non-covered activities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 2. Tiered oversight and administrative burden
Please consider a risk-calibrated, tiered structure is the right goal. The current draft adds new responsibilities for investigators and IBCs, including a Biosafety Assurance, expanded documentation, standardized incident reporting, and new minutes requirements. Many institutions, especially smaller ones and those without dedicated biosafety staff, already operate IBCs with limited resources. If the lowest tier is not truly streamlined, the policy will increase burden while claiming to reduce it. I recommend that NIH:
• Estimate the expected burden on institutions and investigators, and publish it.
• Allow expedited or delegated review for clearly defined low-risk categories.
• Specify what accountability measures apply at each tier, so responsibilities are clear and not duplicative.

3. Continued utility of Risk Groups: 3. Transparency requirements
Public transparency is a legitimate value, and I support it. But expanded disclosure requirements must be balanced against the protection of confidential and proprietary information, unpublished research, and the personal information and safety of investigators and IBC members, who have faced harassment in some contexts. NIH should specify what must be public, in what form, and with what redaction protections, so that institutions are not left to guess and committee members are not discouraged from serving. Transparency should also be weighed against biosecurity: detailed public postings of protocols or agent-specific information could create risks of their own.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): 4. Risk Groups versus Biosafety Levels
Risk Groups are a useful starting point for risk assessment, but they were designed for unmodified agents and do not capture the effect of genetic modification, the specific procedures performed, or the containment available. The BMBL's agent-specific, procedure-based approach to assigning BSLs better reflects actual risk. I recommend that the final policy treat Risk Groups as one input among several, not a rigid baseline, and require assessment of the specific modification, procedure, and scale, with clear guidance on when and why a modified agent should move up or down in oversight.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 5. Compliance, enforcement, and non-NIH-funded research
Applying the policy to non-NIH-funded work at any institution that receives NIH funding gives it broad reach, and I am concerned about fairness and feasibility. Institutions may have to oversee privately or industry-funded work under NIH rules without NIH support for the added cost. I encourage NIH to clarify the legal and administrative basis for this extension, consider phased applicability, and rely on incentives, such as technical assistance and recognition of voluntary adoption, as much as on penalties.
Enforcement should distinguish good-faith reporting of incidents from willful noncompliance. Otherwise institutions and investigators will have reason to under-report, and NIH will lose the information it needs to improve safety.

6. Other feedback relevant to this resource: 6. Implementation resources and guidance
A policy this broad will only work if institutions can implement it. I request that NIH:
• Provide a realistic transition period of at least [12–24] months, with clear effective dates.
• Release plain-language guidance, decision tools, and sample SOPs before the policy takes effect.
• Provide IBC training and consider funding or supplements to support biosafety infrastructure.
• Pilot the incident reporting and minutes templates with a range of institution types and revise them based on feedback.

Description: Conclusion I support NIH's aim of strengthening biosafety oversight in proportion to risk. To succeed, the final policy needs a precisely bounded scope, a truly streamlined low-risk tier, balanced transparency, flexible risk assessment, enforcement that encourages reporting, and adequate time and resources for implementation. Thank you for considering these comments. Sincerely, Karen Ottemann, Distinguished Professor at UC Santa Cruz

355. Ashley Quigley

I am responding: On behalf of myself

Name: Ashley Quigley

Name of Organization: The Kirby Institute, University of New South Wales

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): infectious diseases epidemiology, global biosecurity

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed policy is a constructive and important development because it broadens oversight beyond recombinant or synthetic nucleic acid molecules to include wild-type biological agents, genetically modified organisms, toxins, prions and other self-aggregating proteins [1,2].
However, the proposed scope remains focused largely on physical laboratory research, while biological capability may increasingly develop across a digital-to-biological pathway before conventional laboratory oversight is triggered. AI-generated biological designs may be developed in silico, transferred to a synthesis provider or cloud laboratory, and subsequently assembled or experimentally validated through an automated platform [3-8].
The policy should clarify whether the following activities fall within scope:
• AI-generated, AI-modified or AI-optimised biological sequences, proteins, genomes or other biological designs;
• biological foundation models and genome-language models;
• computational designs intended for synthesis, assembly or experimental validation;
• cloud-accessible and automated laboratories;
• biological foundries integrating computational design with high-throughput experimentation; and
• AI systems used to optimise host range, toxicity, resistance, immune escape, environmental persistence or other biologically consequential properties [3-8].
The recent demonstration that AI-designed bacteriophages could be generated, synthesised and experimentally shown to be viable and biologically functional illustrates why this issue requires attention [3]. The bacteriophages were not human pathogens and should not be interpreted as an imminent human-health threat. Their importance is that they demonstrate a pathway from AI-generated biological designs to functional biological systems.
The policy should distinguish between routine AI-assisted analysis and AI used to design, generate, modify or optimise biological systems. It should also distinguish computational outputs intended only for theoretical analysis from designs intended for synthesis, assembly, experimentation or deployment. Enhanced oversight should be linked to intended use and potential consequences, rather than triggered by the mere use of AI [4-8].

A further consideration is the use of commercial intermediaries. Researchers may obtain synthesis, screening, sequencing, robotic experimentation or other services from external providers. Responsibility may therefore be distributed across researchers, institutions, commercial providers and remote laboratory platforms. The policy should clarify institutional accountability for outsourced work and require applicants to identify relevant providers and the types of activities being conducted [6-8].

I recommend that NIH add a digital biological design and capability component to the policy or provide supplementary guidance addressing this area. This would not require NIH to treat all AI-enabled biology as hazardous. Rather, it would ensure that projects involving potentially consequential biological design are identified early enough for proportionate review.

NIH should also consider a prospective, tiered registry for higher-risk AI-enabled biological design research. The registry could initially cover NIH-funded research involving AI-generated or AI-optimised biological designs intended for synthesis, laboratory assembly or experimental validation. It should record high-level information about the research purpose, biological system, intended downstream activity, use of external providers and biosafety review status without requiring disclosure of sensitive sequences or proprietary methods.

Such a registry could support transparency, accountability, horizon scanning and early assessment of dual-use implications [4,5,9-11]. It should protect legitimate research, intellectual property and national security through tiered access and appropriate confidentiality protections.

This approach is consistent with the distinction between event-based and capability-based surveillance. Existing surveillance asks whether a biological event has occurred. As biological design becomes increasingly digital, NIH should also consider what capabilities are becoming possible, how accessible they are becoming and whether separate advances in AI, synthesis and automation are converging [9-11].

The purpose should be to support expert assessment and preparedness, not to classify legitimate research or researchers as suspicious. Overall, the proposed scope is an appropriate foundation, but it should be expanded or supplemented to address in silico biological design, outsourced experimentation, cloud laboratories, automated biofoundries and the convergence of AI with synthetic biology.

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2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered approach is appropriate and preferable to applying identical requirements to all biological research. The proposed distinction between NIH-level and institutional-level review should reduce unnecessary administrative burden while retaining central oversight for activities with broader or less predictable consequences [1,2].

However, risk assessment should not rely solely on the biological agent, Risk Group or physical containment level. These remain important foundations, but they do not fully capture the risks associated with emerging AI-enabled biological design and technology convergence [3-8].

Risk assessment should also consider:

- the biological function being designed or modified;
- the ability of the design to affect human, animal or plant health;
- host range, transmissibility, environmental persistence or immune escape;
- the potential for increased toxicity, resistance or pathogenicity;
- the extent to which the work reduces existing technical barriers;
- whether the system is novel or poorly characterised;
- whether the design is intended for synthesis, assembly or experimental validation;
- the availability of commercial synthesis or cloud-laboratory services;
- whether several individually low-risk activities are being combined; and
- the degree of automation, remote accessibility and transferability [3-8].

I recommend a two-dimensional risk model. The first dimension should describe the intrinsic biological hazard of the agent, construct or system. The second should describe the capability enabled by the research, including the extent to which the work increases the ability to design, synthesise, modify or deploy a biological system.

This would address situations in which an agent may have a low traditional Risk Group classification but the research substantially increases biological capability. It would also assist with projects in which no conventional pathogen is involved but several technologies combine to reduce the barriers between biological design and implementation [3-8].

NIH-level review should be considered for research that:

- involves RG3 or RG4 agents or equivalent hazards;
- seeks to lower containment for higher-risk agents;
- involves deliberate administration of higher-risk biological products;
- uses AI or automated systems to generate or optimise potentially consequential biological designs;
- links computational design directly to synthesis, assembly or experimental validation;
- creates a capability that could be readily transferred to other systems;
- involves a novel combination of technologies for which existing classifications are inadequate; or

• is distributed across multiple institutions or commercial providers in a way that complicates accountability.

Institutional review should remain appropriate for lower-risk work involving well-characterised systems, established containment requirements and limited potential for harmful capability enhancement. Delegated review may be appropriate for clearly defined low-risk categories, but not where novel AI-enabled designs, automated optimisation or technology convergence make the risk difficult to characterise.
The policy should include a clear escalation mechanism. An IBC should be able to refer a project to NIH when the risk classification is uncertain, the work does not fit an existing category, the project involves a new AI-enabled design capability, several individually low-risk technologies are being combined, or the institution lacks the necessary expertise.

The tiered model should also be adaptive. NIH should periodically review emerging technologies, incident data, scientific developments and evidence from horizon scanning to determine whether additional categories require central oversight [5-8].

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3. Continued utility of Risk Groups: Risk Groups remain useful as a baseline because they provide a common starting point for assessing the inherent hazard of known biological agents. They are valuable for communicating broad biological risk and supporting consistent institutional decision-making [1,2]. However, Risk Groups should not be treated as a complete project-level risk assessment when organisms or biological systems are genetically modified, AI-designed, computationally optimised or placed in a new biological context [1,3-8].

Risk Groups generally describe the properties of an existing biological agent. They may not adequately capture:

• altered host range;
• altered tissue tropism;
• increased environmental stability;
• immune evasion;
• increased toxicity;
• antimicrobial or antiviral resistance;
• altered transmission characteristics;
• changes in replication or persistence;
• novel combinations of genetic elements; or
• AI-designed systems without a close natural analogue [3-8].

BSL and ABSL classifications remain essential for determining containment practices, facilities, equipment and operational controls. However, they should not be treated as a complete assessment of the biological or societal risk posed by a project.

The policy should make clear that RG and BSL/ABSL address different questions:

• Risk Group primarily describes the inherent hazard of the agent or biological system.
• BSL/ABSL describes the containment and operational controls required.
• A project-level risk assessment considers how the modification, experimental purpose, host, route of exposure, scale, automation and downstream use alter overall risk.

For genetically modified or AI-designed systems, the assessment should consider both the starting biological material and the properties or capabilities that the research may create. A modified RG2 agent should not automatically be treated as equivalent to the unmodified agent if the modification changes relevant biological characteristics. Conversely, a non-pathogenic or RG1 system may warrant additional review if the research creates a novel capability with uncertain consequences [3-8].

The policy should provide guidance for systems that do not fit existing RG classifications. IBCs should document the starting agent or system, the genetic or computational modification, the intended biological function, the expected change in hazard, plausible unintended effects, containment requirements and whether the work increases a capability relevant to public health or biosecurity.

I recommend retaining RG and BSL/ABSL as foundational frameworks while adding a supplementary capability and modification assessment for higher-risk or uncertain projects. This would preserve the value of existing biosafety frameworks while reducing the risk that novel AI-enabled biology is classified only according to the closest known agent.

The AI-designed bacteriophage study provides an example of why this additional assessment may be useful. The organisms were not human pathogens, but the research demonstrated that genome-language models can contribute to the generation of complete, viable biological systems [9].

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4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary compliance is important because significant biological capability is developed outside the direct scope of NIH funding, including in biotechnology companies, commercial synthesis providers, cloud laboratories, automated biofoundries and other distributed research environments [1-8].

The NIH should encourage voluntary compliance through a framework that is proportionate, accessible and beneficial to participating organisations. Possible mechanisms include:

- a voluntary institutional registration or assurance pathway;
- model biosafety and responsible-AI policies;
- standardised templates for risk assessment and incident reporting;
- access to training and educational materials;
- recognition for institutions that adopt NIH-aligned oversight;
- confidential consultation with NIH or designated technical experts;
- a voluntary registry for higher-risk AI-enabled biological design research; and
- opportunities for commercial providers and cloud laboratories to demonstrate alignment with the policy [3-8].

The voluntary framework should be available to research that is not NIH-funded but is similar in nature to work covered by the policy. It should also address activities between computational research and physical experimentation, including AI-generated designs, outsourced synthesis, cloud laboratories and automated biological platforms.

A voluntary registry could function as a trusted transparency and horizon-scanning mechanism rather than solely as an enforcement tool. Researchers should be able to register high-level information without disclosing sensitive sequences, proprietary methods or commercially confidential details. Registration could record the broad research purpose, type of biological system, use of AI for generation or optimisation, intended synthesis or experimental activity, use of external providers and institutional review status.

Voluntary compliance is more likely if NIH distinguishes responsible disclosure from evidence of misconduct. Institutions and researchers may be reluctant to report emerging technologies if registration automatically triggers punitive action or public disclosure. The system should support early consultation, learning and proportionate risk management [5-8].

NIH should also consider partnerships with DNA synthesis providers, cloud laboratories, automated foundries, scientific publishers, preprint repositories and relevant professional societies. These organisations may observe changes in biological capability earlier than government agencies or

individual institutions [6-8].
Voluntary compliance should not replace clear minimum requirements where significant risks are foreseeable. It is most appropriate for emerging or uncertain activities, while clearly defined high-risk activities should remain subject to mandatory review.

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1. National Institutes of Health, Office of Science Policy. Draft NIH Policy for Research Involving Biohazards: Table of Changes from the Current NIH Guidelines. August 2026.
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5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The use of standardised incident-reporting and meeting-minute templates should improve consistency, completeness and comparability across institutions. It should also help NIH identify recurring problems and emerging patterns that may not be apparent from individual reports [1,2].
The incident template should distinguish clearly between confirmed laboratory-acquired infection, potential exposure, loss of containment, release with possible community risk, animal escape or injury, non-compliance, failure to obtain or maintain IBC approval, equipment or containment failures, errors in biological design or experimental execution, and incidents involving outsourced or cloud-laboratory activities.
For incidents involving AI-enabled biology or automated laboratory systems, the form should include optional fields identifying whether:
• AI or automated design tools were involved;
• the incident occurred during computational design, synthesis, assembly, experimentation or analysis;
• an external provider was involved;
• a screening, quality-control or containment safeguard failed;
• the incident revealed a gap in the existing risk classification; or
• institutional procedures require updating.
These fields should not require sensitive technical details in a public-facing report. NIH should provide clear guidance on what information should be publicly reported and what information should be submitted confidentially.

The templates should also record corrective and preventive actions, including immediate response, medical or occupational health follow-up, containment and decontamination, notification and escalation, root-cause analysis, corrective action, responsible personnel and review of whether the action was effective.

The meeting-minute template should demonstrate that the IBC considered relevant risk factors without requiring minutes to reproduce every technical detail. It should include fields for:

- project title and responsible investigator;
- biological agents, constructs or systems considered;
- relevant RG and BSL/ABSL classifications;
- genetic, computational or AI-enabled modifications;
- use of synthesis providers, cloud laboratories or automated platforms;
- key risk considerations;
- uncertainty, dissenting views or unresolved issues;
- conditions of approval;
- containment and monitoring requirements;
- incident-reporting obligations;
- decision and vote;
- conflicts of interest; and
- follow-up actions and review dates.

The template should allow institutions to document uncertainty. A project may be approved with conditions while further information is obtained, or referred to NIH because the IBC cannot confidently classify the activity.

This is particularly important because recent studies have identified potential limitations in existing safeguards, including adversarial prompting of DNA language models, recovery of misuse-relevant capabilities through fine-tuning, limitations in nucleic-acid screening systems and circumvention of screening through fragmented orders across multiple providers [3-6].

Public-facing reporting can improve transparency and accountability. However, reports may expose personal information, commercially confidential information, sensitive pathogen information or operational details that could facilitate misuse. NIH should provide guidance on redaction, confidentiality and the distinction between publicly reported and confidentially submitted information.

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regulate fragments as select agents. Nature Communications. 2026;17:3189. doi:10.1038/s41467-025-67955-3.

6. Other feedback relevant to this resource: The implementation resources should include practical guidance for institutions, IBCs, investigators and commercial providers. NIH should provide examples addressing emerging forms of biological research rather than relying only on conventional laboratory scenarios [1-5].

Additional guidance would be beneficial on:

• how to classify AI-generated or AI-optimised biological designs;
• when computational biological research enters the scope of the policy;
• how institutions should oversee work outsourced to cloud laboratories or commercial providers;
• who is responsible for biosafety and biosecurity when research is distributed across multiple organisations;
• how to apply RG and BSL/ABSL frameworks to novel or synthetic biological systems;
• how to assess technology convergence where several individually low-risk activities are combined;
• when delegated review is appropriate;
• when an IBC should refer a project to NIH;
• how to report incidents involving automated or remote laboratories;
• what information should be publicly reported and what should remain confidential;
• how to document AI use without requiring disclosure of proprietary models or prompts; and
• how to distinguish routine AI-assisted analysis from AI-enabled biological design [3-8].

NIH should consider publishing a decision tree or risk-assessment tool that begins with the proposed biological outcome rather than simply asking which agent is being used. It could ask:

1. Is a biological agent, construct, sequence, protein or organism being generated, modified or optimised?
2. Is AI being used to generate or optimise a biological property?
3. Is the output intended for synthesis, assembly or experimental validation?
4. Could the work alter host range, pathogenicity, toxicity, resistance, persistence, immune evasion or transmission?
5. Is the work being conducted through an external provider, cloud laboratory or automated biological facility?
6. Does the project combine multiple technologies that reduce the barriers between design and implementation?
7. Does the project fit an existing RG or BSL/ABSL category?
8. If not, should the project be referred to NIH or an expert review group?

Worked examples should address AI used to analyse sequencing data, protein-structure prediction, design of non-pathogenic enzymes, optimisation of viral vectors, generation of novel genomes for synthesis, cloud-laboratory experimentation and projects combining AI design, DNA synthesis and automated experimentation.

AI-enabled biology is developing rapidly, and static policy categories may become outdated. NIH should establish a periodic review and horizon-scanning process involving biosafety, synthetic biology, computational biology, public health, security and commercial experts [3-8].

The policy would also benefit from a capability-based horizon-scanning function to complement conventional event-based biosafety oversight. Existing systems ask whether a biological event has occurred. A capability-based approach would also ask what biological capabilities are becoming possible,

how accessible they are becoming and whether separate advances in AI, synthesis and automation are converging [9-11].

Relevant upstream signals may appear in scientific publications, preprints, patents, software repositories, synthesis services and cloud-laboratory platforms. The objective would not be to classify legitimate researchers or technologies as suspicious. It would be to identify changes in technological maturity, accessibility and convergence early enough for expert assessment, proportionate safeguards and preparedness measures.

The proposed NIH Biosafety Policy is a significant and necessary modernisation of the existing framework. Its principal strengths are the broader definition of biohazards, clearer institutional responsibilities, tiered oversight, standardised documentation and improved incident transparency.

Its principal limitation is that it remains centred largely on physical laboratory activities, while biological capability may increasingly develop across a digital-to-biological pathway. AI-generated biological designs, computational genome and protein engineering, DNA synthesis, cloud laboratories, automated biofoundries and remote experimentation may operate as connected components of this pathway.

NIH should therefore supplement the policy with explicit guidance on AI-enabled biological design, technology convergence, external providers, capability-based risk assessment and prospective registration of higher-risk AI-enabled biological research. The objective should not be to treat AI-enabled biology as inherently dangerous or to impede legitimate scientific innovation. It should be to identify changing biological capabilities early enough to assess dual-use implications, strengthen safeguards and support proportionate responses.

The policy should continue to ask what biological events are occurring, but the convergence of AI and biology also requires NIH to ask what biological capabilities are becoming possible, how accessible they are becoming and whether existing oversight mechanisms remain adequate.

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1. National Institutes of Health, Office of Science Policy. Draft NIH Policy for Research Involving Biohazards: Table of Changes from the Current NIH Guidelines. August 2026.
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Uploaded File: NIH-Commentary_-additional-material_A-Quigley.pdf

Description: AI-Enabled Biological Design opinion piece and table summarising strengths and weaknesses of the current proposal changes.

AI-Enabled Biological Design: Why Biosecurity Surveillance Must Move Upstream

Authors: Ashley Quigley, Mohana Kunasekaran, Aye Moa, Abrar Ahmad Chughtai and C. Raina MacIntyre

Artificial intelligence (AI) is rapidly changing what is technically possible in biology. Among its most influential developments is generative artificial intelligence, a class of AI systems that learns patterns from existing data and human prompting to create novel content. Recently, research demonstrating that genome language models can generate novel viral genomes that, following synthesis and laboratory assembly, produce viable bacteriophages, provides an important example on how GenAI is expanding the frontiers of biological design and discovery. Sixteen AI-designed bacteriophages targeting Escherichia coli were experimentally demonstrated to be viable and biologically functional (1). These bacteriophages cannot infect humans and do not constitute an immediate human health threat. Their significance for biosecurity lies elsewhere: AI-generated biological designs have now been demonstrated to progress from computational outputs to functional biological systems.

This development illustrates an increasingly connected pathway between digital biological design and physical biological capability and raises an important question for health security: if biological capability increasingly begins in digital environments, are existing approaches to biological-threat surveillance looking in the right places, and early enough? Although this study was formally published in August 2026, it had been publicly available as a preprint on an online repository since September 2025, making it accessible to researchers for approximately 11 months prior to peer-reviewed publication (1,2).

AI is becoming part of the biological capability landscape

AI-enabled generative design is accelerating discovery across chemistry, biotechnology and synthetic biology. Machine-learning systems can generate novel molecules and biological sequences, with substantial potential benefits for medicine, biotechnology and other industries. Large-language models also reduce barriers to access by making highly technical and specialised information easier for non-experts or lay people to understand and use. Biological design tools, by contrast, may expand the capabilities of users with existing technical expertise, enabling more advanced biological design and optimisation. However, the same capabilities create dual-use research of concern (DURC) (3–6). In 2022, researchers demonstrated that a drug-discovery AI could be repurposed by changing its optimisation objective to generate approximately 40,000 potentially toxic compounds, including nerve-agent-like molecules (5).

The recent bacteriophage work extends this discussion from computational generation toward experimentally demonstrated biological function. Its importance is not simply that AI can generate viral sequences. Rather, it demonstrates multiple connected stages in a digital-to-biological pathway: AI can generate novel biological sequences that can subsequently undergo DNA synthesis and laboratory assembly, increasingly supported by automated or cloud-accessible laboratory infrastructure, before progressing to viable biological entities whose function can be experimentally demonstrated.

Important barriers remain. Substantial biological expertise and experimental validation are still required, and computational generation should not be conflated with the ability to produce a biological threat. However, the infrastructure barrier is also changing. Cloud-accessible and AI-native laboratories i.e. laboratories designed from the outset around AI, automation and robotics, rather than conventional laboratories that simply use AI as an additional analytical tool, are increasingly able to remotely coordinate specialised instruments and automate elements of experimental design, synthesis, execution and analysis (7,8). By outsourcing the operation and maintenance of specialised robotic instrumentation to remote providers, these platforms can reduce or eliminate the need for users to purchase costly equipment or be physically present in a laboratory (9,10). Cloud labs are also much harder to track or connect with individuals engaged in nefarious biodesign, as client data are private and not available on any registry. This transition is already evident in platforms such as Emerald Cloud Lab and Strateos (11,12), which enable researchers to design, execute and analyse experiments remotely using highly automated laboratory infrastructure, and in automated biological foundries such as Ginkgo Bioworks, that integrate computational biological design with high-throughput experimental workflows (8,13). These developments suggest that increasing integration of AI with automated and remotely accessible experimentation could rapidly narrow the practical gap between computational design and physical experimentation, with a corresponding increase in difficulty of monitoring such activity for biodefense.

This convergence matters because biological risk is shaped by the capabilities that emerge when technologies are combined. Over the past decade, AI applications in biology have evolved from analysing and predicting biological properties towards designing novel molecules, proteins and genomes, and increasingly connecting these computational designs with experimental systems capable of demonstrating biological function (Figure 1).

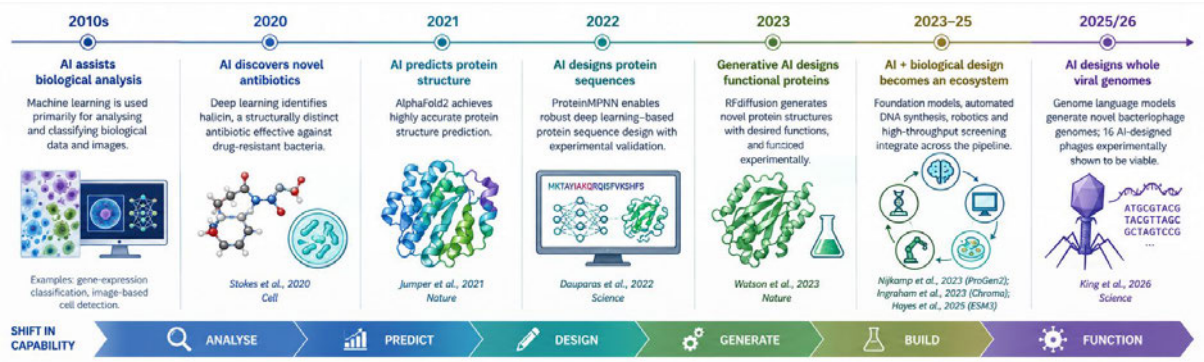


Figure 1. The Evolution of AI in Biological research: from prediction to functional biological systems: A timeline of selected milestones illustrating accelerating capabilities and expanding impact (1,14–20).

The biosecurity intelligence problem is changing

Traditional chemical and biological threat intelligence has relied substantially on physical indicators: acquisition of biological materials, specialist laboratories, unusual procurement, production

infrastructure and other observable activities. These remain important indicators. However, AI-enabled biological capability can begin much further upstream in digital environments and develop within legitimate scientific, academic and commercial ecosystems.

Event-based surveillance asks whether a biological event is occurring or has occurred. It seeks signals such as unusual disease, outbreaks, laboratory confirmation or evidence of deliberate release. Capability-based surveillance asks an earlier question: are the technological conditions that could enable future biological threats changing?

The two approaches are complementary. Conventional epidemiological and intelligence surveillance remains essential. However, as biological design becomes increasingly digital, an additional layer of surveillance may be required to identify upstream changes in technological capability while there is still time to assess their significance.

Relevant early signals may increasingly appear in scientific publications and preprints, patents, software repositories, technical reports and specialist discourse before conventional physical indicators become visible (21). Existing intelligence approaches are not necessarily designed to integrate these heterogeneous signals or assess how converging advances in generative AI, biological design, synthesis and automation collectively change biological capability (22–24). We therefore propose a distinction between event-based surveillance and capability-based surveillance. Surveillance should also capture upstream and downstream signals. Upstream signals could include sequence orders, cloud-laboratory use and protocol screening; downstream signals could include genetic signatures or mutations, with tools such as metagenomics used to flag novel pathogens.

Moving the surveillance window upstream and the role of open-source intelligence (OSINT)

Capability-based surveillance should not focus narrowly on identifying individual technologies as “threats.” AI-enabled biological design, DNA synthesis, synthetic biology and laboratory automation all have important legitimate applications. Their presence alone provides little information about malicious intent. Instead, the relevant unit of analysis may increasingly be technological convergence.

Potential indicators could include changes in the maturity and accessibility of biological foundation models; advances in AI-enabled molecular, protein or genome design; integration of generative models with synthetic-biology platforms; developments in DNA synthesis and laboratory automation; and evidence that previously separate technologies are becoming technically interoperable (25–27). Monitoring enabling technologies is particularly important because increasing feasibility may arise not from a single breakthrough, but from the progressive removal of barriers between design and implementation. This requires surveillance systems capable of identifying relationships among technologies rather than simply counting references to particular threats.

OSINT offers one mechanism for doing this. Scientific publications (including both peer reviewed and pre-prints), patents, software development and technical discourse provide observable information about technological development across geographically distributed research ecosystems. AI-enabled approaches, including natural-language processing and temporal trend analysis, may allow these information streams to be analysed systematically for changes in terminology, technological maturity and convergence.

There is precedent for using OSINT to complement conventional biological surveillance. AI-enabled epidemic early-warning approaches have demonstrated that open-source information can identify infectious-disease signals when conventional reporting is delayed or incomplete (28–30). OSINT has also been applied to health-security contexts outside conventional epidemic surveillance, including the detection of radiological events following the invasion of Ukraine (31).

The next challenge is whether similar principles can be applied further upstream, not simply to detect biological events, but to characterise changes in the technological environment from which future biological risks could emerge. Moving surveillance upstream also creates risks. The majority of AI-enabled biological research is undertaken for legitimate scientific, medical or commercial purposes. A publication describing a new biological model, an advance in DNA synthesis or the release of scientific software does not indicate malicious intent. Nor can OSINT alone establish intent. Capability-based surveillance must therefore avoid treating legitimate scientific innovation as inherently suspicious.

The objective should instead be to provide situational awareness of changing capability. Individual indicators would have limited meaning in isolation. Their value may emerge when multiple independent signals suggest increasing technological maturity, accessibility or convergence. This distinction should also inform governance. Safeguards applied to individual AI models may form one component of risk reduction, but such controls may be circumvented through techniques such as jailbreaking, or bypassed when models may be modified, fine-tuned or combined with other biological technologies. Findings from the GeneBreaker framework indicate that adversarial prompts may enable generative models to produce genome-like sequences resembling known pathogens, such as SARS-CoV-2 and HIV, with high levels of sequence homology (32). A Microsoft study showed that even with software patches, approximately 3% of biothreat designs still evaded the screening software used by DNA synthesis suppliers (33). It was also demonstrated how an AI-powered drug discovery tool could be used to generate blueprints for plausible novel toxic chemicals that could serve as chemical weapons (5). In an MIT study, a chatbot suggested four potential pandemic pathogens in a single hour and explained how they could be generated from synthetic DNA, supplied the names of DNA synthesis companies unlikely to screen orders and identified detailed protocols and how to troubleshoot them (34). Fine-tuning the Evo 2 model on 110 harmful human-infecting viruses rescued its ability to identify SARS-CoV-2 immune escape variants, demonstrating that pre-training data filtering is an insufficient safeguard (35).

Effective biosecurity will therefore increasingly require consideration of the wider technological ecosystem, including where meaningful barriers remain and where they may be eroding. Recent red-team testing of commercial nucleic acid synthesis demonstrated the importance of assessing safeguards at the system level: Edison and colleagues showed that individually unregulated DNA fragments could be obtained across multiple synthesis providers in combinations sufficient to circumvent existing controls, highlighting vulnerabilities that may not be apparent when individual transactions are considered in isolation (36). Such surveillance should support proportionate expert assessment rather than automated classification of research as benign or threatening. Its purpose is to help decision-makers recognise technological change early enough to consider whether additional assessment, safeguards or policy responses are warranted.

Existing research ethics and biosafety frameworks may not fully capture AI-enabled biological design at the stage where potentially consequential capabilities first emerge. Conventional oversight is generally triggered by research involving humans, biological materials, genetically modified organisms or physical experimentation, whereas AI-generated biological designs may initially exist entirely in silico. This creates a potential governance gap in which computational capabilities can develop before traditional ethical or regulatory oversight is engaged. Prospective registration of higher-risk AI-enabled biological design research could therefore provide an additional mechanism for transparency, accountability and early assessment of dual-use implications. The development of a prospective registry for AI-enabled biological design research, analogous in principle to clinical-trial registration. Research involving AI-generated, modified or optimised biological designs intended for physical synthesis or experimental validation could be registered prospectively, providing greater transparency around the transition from computational design to experimental biology. Such a registry could support responsible research norms and horizon scanning while avoiding disclosure of sensitive technical or proprietary information.

From detecting events to anticipating capability

The demonstration of viable AI-designed bacteriophages does not signal an imminent biological-weapons threat. It does, however, provide a timely illustration of why the relationship between digital biological design and physical biological capability deserves greater attention from the biosecurity community. As AI-enabled biological design converges with DNA synthesis, synthetic biology and laboratory automation, some of the earliest indicators of changing biological capability may increasingly appear in the digital scientific environment before traditional physical or epidemiological warning signals emerge.

Biosecurity surveillance should evolve accordingly. The objective is not to replace existing epidemic surveillance, laboratory systems or traditional intelligence approaches, but to complement them by moving part of the surveillance window upstream. Systematic monitoring of scientific, technological and open-source signals could help identify changes in biological capability while decision-makers still have an opportunity to assess risk, strengthen safeguards and prepare proportionate responses.

Biological-threat surveillance must continue to ask, ‘What biological events are occurring?’ But the convergence of AI and biology requires us to ask earlier: “What biological capabilities are becoming possible?” and “are bad actors intending to use or using these technologies?” Answering that question may be an important component of anticipatory biosecurity in the age of AI.

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Strengths, Limitations and Emerging Biosecurity Gaps in the Draft NIH Biosafety Policy

Authors: Ashley Quigley, Mohana Kunasekaran, Aye Moa, Abrar Ahmad Chughtai and C. Raina MacIntyre

Area of proposed change	Strengths	Limitations and recommended improvements
Scope and definition of biohazards	Broadens oversight beyond recombinant and synthetic nucleic acid molecules to include wild-type biological agents, genetically modified organisms, toxins, prions and other self-aggregating proteins.	The proposed scope remains focused largely on physical laboratory research. It may therefore leave a gap where biological capability develops first in silico through AI-generated or AI-optimised sequences, proteins or genomes before synthesis or experimental validation occurs.
Institutional submissions and assurances	Provides a clear accountability structure and reduces repetitive reporting through a four-year assurance period.	Institutions may not have full visibility over work conducted through commercial synthesis providers, cloud laboratories, automated facilities or international partners. Because responsibility may be distributed across several organisations, the policy should clarify who is accountable for identifying and managing the associated biosafety and biosecurity risks.
Institutional Biosafety Committees	Maintains IBC oversight and requires institutions to keep current membership information, supporting local accountability.	IBC expertise may not always extend to genome-language models, computational protein design, AI-enabled dual-use risks, autonomous experimentation or biological foundries. NIH should provide guidance on accessing appropriate expertise in AI, synthetic biology, computational biology and biosecurity.
Tiered oversight and risk calibration	The distinction between NIH-level and institutional-level review is proportionate and should reduce unnecessary administrative burden for lower-risk research.	Risk assessment should not rely solely on Risk Group, BSL/ABSL or the physical agent involved. It should also consider what capability the research creates, how accessible that capability is, and whether several individually low-risk technologies are being combined
Risk Groups and BSL/ABSL classifications	Risk Groups remain useful for describing the inherent hazard of known agents. BSL and ABSL classifications remain essential for determining containment and operational controls.	These classifications do not by themselves capture the capability created through genetic modification, computational optimisation or technological convergence. NIH should retain them as foundational frameworks but add a project-level capability and modification assessment

Area of proposed change	Strengths	Limitations and recommended improvements
Lowering of containment	Provides clearer distinctions between NIH approval and IBC approval for lowering containment, particularly for RG2, RG3 and RG4 agents.	The policy should clarify how containment decisions apply to AI-designed or synthetic systems without an established Risk Group. Where the biological properties or consequences of a novel system are uncertain, the IBC should have a clear pathway to seek expert or NIH advice.
Delegated review	May improve efficiency for clearly defined lower-risk research and allow IBCs to focus on more complex projects.	It should not be used where novel AI-enabled designs, multiple converging technologies or substantial uncertainty make the risk difficult to characterise. NIH should specify exclusion criteria and escalation pathways.
Incident reporting	Standardised incident categories should improve consistency, institutional learning and NIH's ability to identify recurring problems.	The templates should also capture incidents occurring across the digital-to-biological pathway, including AI-enabled design errors, automated laboratory failures, cloud-laboratory incidents, synthesis-screening failures and incidents involving external providers.
Public reporting of incidents	Public-facing reporting can improve transparency and accountability.	Reports may expose personal information, commercially confidential information, sensitive pathogen information or operational details that could facilitate misuse. NIH should provide clear guidance on redaction, confidentiality and the distinction between publicly reported and confidentially submitted information.
Meeting-minute documentation	A standardised template should improve consistency and demonstrate that relevant risks were considered.	It should also allow IBCs to document uncertainty, dissenting views, conditions of approval, use of AI or external providers, technology convergence and reasons for referral to NIH or expert review.
Clinical research	Appropriately identifies higher-risk clinical research involving shedding, replication, integration, higher-risk manipulations and RG2 or higher wild-type agents.	AI-designed or AI-optimised products may not fit existing categories. Guidance is needed where computational optimisation changes biological properties or creates uncertainty about clinical risk.
Genetically modified plants	Excluding genetically modified plants and non-human-pathogenic plant pathogens may reduce unnecessary regulation of lower-risk plant research.	Plant, environmental and agricultural systems may still create ecological, food-security or economic risks. NIH should clarify how novel AI-designed plant pathogens and environmental systems interact with other oversight frameworks.
Commercial providers, cloud laboratories and	The institutional assurance model could encourage institutions to take	Biological capability may be distributed across researchers, synthesis companies, cloud laboratories and automated biofoundries. The

Area of proposed change	Strengths	Limitations and recommended improvements
Automated biofoundries	responsibility for research conducted through external providers.	policy should clarify provider disclosure, institutional responsibility and how oversight is maintained across these interfaces.
Voluntary compliance outside NIH funding	Could extend responsible biosafety and biosecurity practices to biotechnology companies, private institutions, commercial laboratories and other non-NIH organisations.	Participation may be limited if compliance creates administrative burden or punitive scrutiny. NIH should provide model policies, training, confidential consultation and recognition for voluntary alignment, while retaining mandatory requirements for clearly defined high-risk activities.
Prospective registration	A registry could support transparency, accountability and horizon scanning for higher-risk AI-enabled biological design research.	It could identify research involving AI-generated or AI-optimised designs intended for synthesis, assembly or experimental validation without requiring disclosure of sensitive sequences, proprietary methods or information that could create security risks.
Capability-based surveillance	Could complement event-based biosafety oversight by identifying emerging biological capabilities before an incident occurs.	As biological design becomes increasingly digital, NIH should also consider what capabilities are becoming possible, how accessible they are becoming, and whether separate advances in AI, synthesis and automation are converging. Relevant upstream signals may appear in publications, preprints, patents, software repositories, synthesis services and cloud-laboratory platforms.
Implementation guidance	Provides a foundation for modernising NIH biosafety oversight and standardising institutional practice.	NIH should publish worked examples and a decision tool covering AI-assisted analysis, AI-generated sequences, genome-language models, computational protein design, cloud laboratories, automated biofoundries and technology convergence. Guidance should distinguish routine AI-assisted analysis from AI-enabled biological design.
Future policy review	The framework can potentially be updated as biological research develops.	AI-enabled biology is developing rapidly, and static policy categories may become outdated. NIH should establish a periodic review and horizon-scanning process involving biosafety, synthetic biology, computational biology, public health, security and commercial experts. This would allow oversight to adapt as the barriers between digital design and physical biological experimentation change.

356. Ted Acott, PhD

I am responding: On behalf of myself

Name: Ted Acott, PhD

Name of Organization: Oregon Health & Science University

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Glaucoma Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We use human eye bank eyes for trabecular meshwork primary cell culture and for anterior segment organ culture. Occasionally, other portions of these eyes are also used for primary cell or organ culture, although this is not our primary focus. Research tissue is not screened by local eye banks for infectious agents, although transplantation tissue, which we seldom get is. We pay $1,335 for a pair of human eye bank eyes, normal or glaucomatous. In a single year, our group often pays $50,000 to as much as $100,000 just to obtain enough eye bank eyes to conduct statistically significant outcomes to our critically significant research questions. We do not do any animal research, only using human tissue. This is the best model for understanding human glaucoma and for working out treatments to translate to clinical glaucoma therapy. All of our work is thus basic science with the eventual goal of moving it to clinical glaucoma therapy. Since the eye bank does not screen this tissue for infectious agents, we presume that it is all contaminated with some nasty contagious infectious agents and treat all tissue with appropriate precautions. If this tissue became subjected to IBC review and if additional screening were required, who would pay the thousands of dollars this would cost? IBC and NIH would not, so this would likely shut down our several very key fully funded NIH?NEI research projects funded by NEI R01, R21, STTR and P30 grants. The fact that we are highly funded and I have been for over 44 years without any incidents suggest rather strongly that our work is of very high biomedical significance for developing much-needed glaucoma therapy. Since we do not get any specific donor information, we do not have to deal with human subjects requirements by NIH. That alone would require that we hire a person to handle that requirement and no one will pay for it so someone has to give up considerable research time to go through this process. Requiring IRB compliance for the many human eye bank eyes we buy every year would similarly take considerable time from our actual research to deal with the IRB compliance. If in addition, we had to go through extensive testing for infective agents, we would not be able to use the eye bank eyes within the short window of time that they are viable and would not be able to afford the testing for the many possible infective agents. This would kill our highly funded research projects to develop sourly needed new glaucoma therapies.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Additional oversight would be extremely detrimental to our glaucoma research NIH grants and would serve no function. We

are already treating this tissue as though it was dangerously infectious and this would serve no useful function and would devastate our very important research programs.

3. Continued utility of Risk Groups: We already use high risk BSL 2+ containment and biosafety for all tissue and extracts, so additional oversight would serve no purpose but would add another obstacle to our already very careful research progress.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): We already use very strong "voluntary" compliance for the safety of our employees and ourselves. Additional oversight would not improve this. We train all of our employees that have any contact to human tissue, directly or otherwise, to follow our strict safety policies.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We have never had any incidents, but would certainly report any if they occurred and take all precautions.

6. Other feedback relevant to this resource: Our research is already difficult enough and very expensive and human tissue is also quite expensive. Adding the burden of another layer of oversight and compliance to what we do now would serve no additional safety purpose and would encumber our research progress and add additional expense to our already very expensive tissue use. Human tissue is the best model for human glaucoma and we are already doing everything necessary to avoid any danger to our employees and ourselves.

357. Adelaide University

I am responding: On behalf of an organization

Name: Camilla Liddy

Name of Organization: Adelaide University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Medical and scientific research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Policy should serve as a requirement for NIH-funded research, or institutions, where high-risk biological research is proposed (i.e. Select Agents, RG3 or RG4 microorganisms, or gene drive modified organisms) as these can pose risks of greater international significance. For lower risk research (RG2 and genetically modified RG2 organisms managed under an appropriate local framework) the NIH should recognise the provisions of the recipient's local jurisdiction and not impose additional requirements beyond providing a voluntary framework to fill any existing gaps in the recipient's local requirements.

The scope of the policy is very broad and is likely to be problematic in jurisdictions where there are competing regulatory requirements. Potential issues from an international perceptive include:

Regulatory incompatibility.

Australia has its own legislation (E.g. Commonwealth Gene Technology Act 2000) and standards (e.g. AS/NZS 2243.3) that align well with international equivalents and also take into account non-health related factors such as potential impacts on biosecurity and trade. Organisations needing to assess proposed research under multiple policies with different priorities and scope will lead to unnecessary complexity.

It is noted there is no allowance in the new policy for precedence (e.g., if there is conflict that local legislation/regulations will apply). The proposal for removing the absolute requirement for adherence to the new policy and replacing it with a registration process for international institutions operating under equivalent regulatory frameworks could address these in the global context.

For international institutions, such as those who are accredited by their Regulator or who otherwise operate within the local regulatory and compliance requirements, should be able to register their Institutional Biosafety Committees (IBC) with the NIH instead of being required to comply with the new policy. This approach is risk-proportionate, allowing institutions to operate within their own applicable

regulatory and compliance frameworks whilst enabling the NIH
to have oversight and awareness of this through the NIH governance process. This mirrors, for example, the approach taken for animal research, human research, and research integrity between international and US agencies. A part of the registration monitoring process could be regular reporting to the NIH to continue registration, and time limitations on the registration (again, similar to the arrangements for human research and animal research).

The intention of the policy to apply to all research regardless of funding source, which could interfere with contractual obligations to funders who, for example, require compliance with, in our case, Australian regulatory frameworks.

Composition and other administrative requirements for IBCs that are not aligned with the Australian context or regulatory expectations or requirements.
Significant administrative burden over and above the significant and appropriately calibrated administrative compliance and governance activities institutions already adhere to in order to satisfy complex and intersecting local regulatory and compliance requirements. This includes, but is not limited to, biosafety, general bio-compliance, and occupational health, safety and welfare legislation and regulatory requirements under Federal (national) and State/Territory legislation, regulations and standards.

Tension between the expectations of the new policy and local regulatory or institutional accreditation requirements have real potential for creating an environment for non-compliance, whether Inadvertently, unavoidably, or unintentionally, with the new policy, Australian legislation/regulations/standards/accreditation requirements, or contractual requirements (including funding rules, as may apply).

'GDMO' is not defined.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered approach is generally appropriate in a complicated regulatory environment such as biosafety. However as described elsewhere in our response, this new policy does not allow for integration with international regulatory frameworks and existing policy and procedural frameworks that comply with local regulations (in the Australian context these include Federal, State/Territory and National Standards requirements for both bio-compliance research and occupational health, safety and welfare). The requirements of the new policy are problematic to implement where the policy requirements conflict with local regulatory compliance or other requirements.

3. Continued utility of Risk Groups: Nomenclature in the Australian context is different and should be accounted for to enable ease of compliance. Noting that reducing the scope of research/organisations required to comply with the policy, or an equivalency arrangement (such as registration of international IBCs) could address this.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The Policy can serve as the basis for a voluntary compliance framework for research where there are gaps or uncertainties in the recipient organisation's

equivalent local biosafety frameworks. These appear to be appropriately captured, whilst not requiring adherence they encourage adoption of gold standards for all institutions conducting biosafety research.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The requirement to use these templates, especially where these are required for publicly accessible publication, is problematic where they interfere with minutes captured through compliance systems that have their own format of minutes, as is the case for Adelaide University for its IBC and health, safety and welfare aspects. Some flexibility in this approach to the format, whilst ensuring appropriate levels of information is captured in local formats, would be preferable.

6. Other feedback relevant to this resource: N/A

358. Mary Kelley, PhD

I am responding: On behalf of myself

Name: Mary Kelley, PhD

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): adult stem cells and glaucoma

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: This policy's scope would not be appropriate for the research performed in my lab. As glaucoma researchers, we already treat each pair of human eyes and corneal rims as potentially very hazardous, although they generally are not. All of our specimens are subjected to dissection in a laminar flow hood under sterile conditions, and our research personnel wear appropriate personal protective gear. We do not accept any eyes or corneal rims from the local eye bank known to be from patients who had been diagnosed with sepsis, HIV, or infectious diseases. If we do not receive these eyes or rims within 4-6 hours of death, they must be placed in culture immediately, or they will be unuseable for our research, as further testing would result in delays. The specimens are then placed in a typical laboratory incubator for cell or organ culture in flasks or 6-well plates for experimental procedures. All waste that touches the specimens, their media, or equipment is then either placed in a red hazardous bag tied tightly for incinerator disposal, instruments and beakers are sterilized with autoclaving or with bleach, and media is diluted with 20% bleach for half an hour or overnight. We clean the dedicated culture rooms thoroughly (P2 level only) and apply UV sterilization to the surfaces and room. We do not have live patients as a part of our experiments, so we are technically (by NIH) not considered to be human subjects research. I do not think that there is additional oversight needed for these purposes, as we maintain strict laboratory procedures to keep all personnel safe. Our eye bank eyes arrive in a special solution to keep them viable, and we never touch the specimens except with surgical tools in the hoods. These tools are then placed in a disinfecting tool sterilizing solution prior to autoclave treatment. If there were a potential danger to the public, then it would be valuable for NIH to know about it and put out a warning without naming researchers or their university, but there are such strict procedures in place with our lab and the university that it is a highly unlikely situation, especially with the type of research we are doing. Additional oversight would be quite expensive for our low risk area, as it would delay our work, mess up the timing and viability of our specimens, and result in much more expense not covered by the university or NIH. We already pay so much for human eye specimens as it is.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I do not see tiered oversight as being critical to the research we do with glaucoma, as our present system, where we are monitored by the university's IBC is quite appropriate and would increase the administrative burden

considerably. The risk is managed quite well by our university's IBC and our own self-monitoring. We are super cautious about working with tissues and cells, and keep the culture rooms' hoods and equipment in very highly maintained condition (laminar flow hoods checked professionally on a regular basis). We do not have additional time to devote to this, as we are already performing at a very high level of safety for our low risk experiments.

3. Continued utility of Risk Groups: We are at a lower risk level and are subject to procedures that nearly eliminate that as well. See above for more information considering safety.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Possibly these non-NIH funded institutions could set up an IBC group from other universities on a voluntary basis, with the incentives that this could be used on the IBC review researcher's CV as a positive attribute.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Protein aggregation is not well-defined in this policy, and many proteins aggregate. While it is true that something such as prion-research could be hazardous, still that does not mean it should not be done. Perhaps valuable health information may result from such research, although it should be limited to labs able to be at a higher biosafety level because of the higher risk. It probably already is restricted to that now anyway.

359. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I strongly oppose the new policy. A modification that is not permanent or transferrable to offspring poses no threat to public or environmental health. As the RNA society stated "This re-classification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research and in recombinant vaccine technologies, with potentially devastating public health outcomes."
This policy is a disservice to health sciences, and therefore life, as a whole.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

360. European Biosafety Association

I am responding: On behalf of an organization

Name: Pat G Casey

Name of Organization: European Biosafety Association

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: EBSA-NIH-response.docx

Description: Consultation response by the European Biosafety Association

EBSA Submission — Draft NIH Biosafety Policy for Research Involving Biohazards

EBSA welcomes the proposed Policy

The European Biosafety Association (EBSA) is the professional association for biosafety practitioners in Europe, and we welcome NIH's decision to modernise its oversight framework. We comment as an international stakeholder rather than as a funded party. For nearly fifty years the NIH Guidelines have operated as a *de facto* global reference; whatever replaces them will be read and copied internationally.

Our comments are therefore confined to points where a European perspective adds something NIH is unlikely to hear in volume from US respondents.

1. Recognise equivalent national oversight for research outside the United States

Section II applies the Policy to non-NIH-funded research at any institution receiving any NIH funding. For a European university holding a single NIH sub-award, this layers US institutional requirements onto work already regulated under Directive 2009/41/EC on the contained use of GMMs, Directive 2000/54/EC on biological agents at work, and national implementing regulations, typically with notification to or consent from a national competent authority.

Section II already allows research under another federal agency's purview to proceed under that agency's oversight. We suggest an analogous accommodation for non-US sites: where research is authorised by a national competent authority under an established statutory biosafety framework, that authorisation should be accepted as satisfying the Policy's containment determination, with the Assurance recording the framework relied upon. Absent such a provision, institutions face duplicated and occasionally conflicting determinations, and some will decline NIH funding rather than restructure their oversight. We would also note that six months from publication is a short transition where national authority processes must be realigned.

2. State IBC requirements functionally rather than structurally

Section III-B specifies the IBC by composition: at least five members, two unaffiliated with the institution, a BSO as a voting member for BSL-3/4 and GDMO work. European institutions generally discharge the same functions through differently constituted bodies, and the unaffiliated community member has no counterpart in most national frameworks; recruiting two is difficult for smaller institutions and awkward in some national contexts.

We suggest the Policy express these requirements as the competences and independence the review must demonstrate, allowing an institution to show how its existing committee meets them. The same applies to the BSO role, which in many European institutions sits with a biological safety adviser or research safety officer appointed under national occupational safety law.

3. Reconcile the publication requirements with data protection law

Mandatory public posting of IBC minutes and incident reports, retained for five years, is not straightforwardly lawful in the EU. Incident reports concern identifiable individuals and their health, which is special category data under Regulation (EU) 2016/679 (GDPR); publication requires a legal basis that a US funding condition does not supply. In an institution with one BSL-3 laboratory, de-identification is largely nominal.

We support the transparency objective. We suggest NIH state that the publication requirement applies subject to applicable national data protection and employment law, and issue redaction guidance alongside the templates, including a minimum content standard for a published report so that institutions are not left choosing between non-compliance and over-redaction.

4. The definition of genetic modification is broad

The Section II definition captures stable alterations introduced "by passaging, reassortment, chemical or radiological means". This is materially broader than the EU position, where Annex II of Directive 2009/41/EC excludes mutagenesis from the techniques treated as genetic modification for contained use.

The effect is to bring routine, long-established and generally low-risk microbiology into scope: serial passage, chemical mutagenesis, selection of resistant mutants. This sits awkwardly with the stated aim of removing red tape from low-risk research. We suggest either narrowing the definition or making clear in the implementation resources that such work ordinarily falls to delegated review under Section IV-3.

5. The National Biosafety Data and Safety Analysis Center should be opened internationally

The NBDSAC is, in our view, the most consequential proposal in the draft, and we support it without reservation. Non-punitive, de-identified reporting of near-misses and secondary failures is how aviation and healthcare built their safety evidence base. Biosafety has no equivalent anywhere, and incident data is scarce in every jurisdiction.

Two suggestions. The protection against enforcement use should be made as legally robust as can be arranged, since participation will collapse at the first instance of voluntarily submitted data being used adversely. And the Center should be designed from the outset to accept voluntary submissions from non-US institutions and to publish aggregate findings openly. EBSA would welcome the opportunity to contribute to that work and to connect it to European practice.

Closing

The draft Policy's ambition to serve as a model framework beyond the institutions NIH funds is well judged, and the points above are offered in support of that ambition rather than against it. EBSA would be glad to engage further as the Policy is finalised and the implementation resources are developed, particularly on international workability and on the design of the NBDSAC.

Submitted on behalf of the European Biosafety Association.

Pat G. Casey, President, European Biosafety Association; ebsa-office@ebsaweb.eu

361. Allyssa Baptista

I am responding: On behalf of myself

Name: Allyssa Baptista

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: • The scope and definitions in the draft policy require clarification. As written, the policy would be difficult for my institution to implement. Its scope should be clearly defined and focused on research typically conducted at BSL-2 or higher containment. Definitions of zoonotic agents, emerging agents, biological toxins, and self-aggregating proteins need clear criteria and examples of what is and is not covered.
• The expanded definition of genetic modification to include passaging, reassortment, and chemical/radiological means is too broad. It could encompass natural processes and would be extremely difficult for IBC's to interpret and register consistently.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): • Delegated review is a welcome addition, but it should streamline IBC review rather than expand it to include activities that should be outside the Policy's scope, such as work with established cell lines, transgenic organisms at ABSL-1, or genetic modifications and genetically modified organisms at BSL-1.
• A recurring theme throughout the NIH listening sessions was the need to reduce administrative burden and focus limited IBC and Biosafety Officer resources on higher risk projects or activities. The final section of the Draft Policy proposes a risk-based approach to assigning containment levels and risk-mitigation measures, which I support. However, other sections could increase administrative burden by requiring IBC's to review lower-risk activities and could significantly delay approval if institutions must petition NIH to assign containment levels for agents lacking a risk-group classification or recommended containment level in the BMBL.
• Allow IBCs to assign containment levels of BSL-2 and below using scientific literature and a risk-based assessment. Reserve NIH consultation for higher-risk agents requiring BSL-3 or higher containment, or for truly novel organisms that may require containment above BSL-2.

3. Continued utility of Risk Groups: • Risk Groups are distinct from Biosafety Levels. Risk Groups still give a general idea of the overall risk of the agent. If they a removed and replaced with Biosafety Levels, BSL would have to be redefined to include both risk levels and containment/risk mitigation methods. It might make things simpler for researchers to understand, but loses some of the nuance.
• The BMBL was never meant to be a regulatory document. It is a guidance document. It also focused

mainly on pathogens, so many non-pathogenic organisms are missing and lack both guidance on BSL and an assigned RG classification. These organisms should NOT require petitioning the NIH to assign biosafety levels if there is sufficient literature support to handle the organisms at BSL-1 or BSL-2. I would support having IBC's to do a risk assessment based on literature and location controls in this process.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: • Current incident-reporting and public-posting requirements could discourage members of the research community from reporting incidents because of concerns about sanctions such as loss of funding or reputational harm. Reduced reporting could undermine overall safety and inadvertently contribute to more serious incidents.
• Requiring IBCs to use the NIH template for meeting minutes, without flexibility to use institutional formats, would create significant administrative burden. The currently required level of detail is unlikely to meaningfully improve transparency or the effectiveness of IBC review.
• Provide templates for incident reports and IBC minutes as optional examples that institutions may adapt, rather than as required formats. Permit institutions to post redacted incident reports and meeting-minute summaries that provide adequate transparency while protecting confidential or sensitive identifying information.

6. Other feedback relevant to this resource: • Provide templates for incident reports and IBC minutes as optional examples that institutions may adapt, rather than as required formats. Permit institutions to post redacted incident reports and meeting-minute summaries that provide adequate transparency while protecting confidential or sensitive identifying information.
• Provide training materials and other implementation resources to help institutions meet the new requirements and inform their research communities about the revised processes.
• Consider convening a working group or expert panel that includes representatives of the biosafety, IBC, and research communities to review and revise the draft Policy.
• Provide an additional opportunity for public comment on the revised draft.
• Extend the implementation period to at least two years.

Uploaded File: NIH_Comment_AAB_10.19.26.docx

Description: Support letter and additional comments.

Subject: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Support for CSHEMA Recommendations

To Whom It May Concern:

I am submitting this comment in response to the National Institutes of Health (NIH) effort to modernize and strengthen the oversight of biosafety.

I support the comment submitted by the **Campus Safety, Health, and Environmental Management Association (CSHEMA)** regarding this effort. CSHEMA's comment appropriately reflects the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

As an individual Biosafety Manager, my work would be directly impacted by a new NIH policy on biosafety and I support the recommendations outlined by CSHEMA.

Of particular concern are the following points:

- The scope and definitions in the draft policy require clarification. As written, the policy would be difficult for my institution to implement. Its scope should be clearly defined and focused on research typically conducted at BSL-2 or higher containment. Definitions of zoonotic agents, emerging agents, biological toxins, and self-aggregating proteins need clear criteria and examples of what is and is not covered.
- Delegated review is a welcome addition, but it should streamline IBC review rather than expand it to include activities that should be outside the Policy's scope, such as work with established cell lines, transgenic organisms at ABSL-1, or genetic modifications and genetically modified organisms at BSL-1.
- The expanded definition of genetic modification to include passaging, reassortment, and chemical/radiological means is too broad. It could encompass natural processes and would be extremely difficult for IBC's to interpret and register consistently.
- Current incident-reporting and public-posting requirements could discourage members of the research community from reporting incidents because of concerns about sanctions such as loss of funding or reputational harm. Reduced reporting could undermine overall safety and inadvertently contribute to more serious incidents.
- Requiring IBCs to use the NIH template for meeting minutes, without flexibility to use institutional formats, would create significant administrative burden. The currently required level of detail is unlikely to meaningfully improve transparency or the effectiveness of IBC review.
- A recurring theme throughout the NIH listening sessions was the need to reduce administrative burden and focus limited IBC and Biosafety Officer resources on higher risk projects or activities. The final section of the Draft Policy proposes a risk-based approach to assigning containment levels and risk-mitigation measures, which I support. However, other sections could increase administrative burden by requiring IBC's to review lower-risk activities and could significantly delay approval if institutions must petition NIH to assign containment levels for agents lacking a risk-group classification or recommended containment level in the BMBL.

- A six-month implementation period after publication of the final policy is not feasible. Institutions need sufficient time to understand the new requirements, identify gaps in existing registrations, update registration systems and processes, and train their research communities.

I feel the suggestions in CSHEMA comment do a good job at addressing these points. I would like to stress the following and add addition recommendations:

- Provide templates for incident reports and IBC minutes as optional examples that institutions may adapt, rather than as required formats. Permit institutions to post redacted incident reports and meeting-minute summaries that provide adequate transparency while protecting confidential or sensitive identifying information.
- Allow IBCs to assign containment levels of BSL-2 and below using scientific literature and a risk-based assessment. Reserve NIH consultation for higher-risk agents requiring BSL-3 or higher containment, or for truly novel organisms that may require containment above BSL-2.
- Consider convening a working group or expert panel that includes representatives of the biosafety, IBC, and research communities to review and revise the draft Policy.
- Provide an additional opportunity for public comment on the revised draft.
- Extend the implementation period to at least two years.
- Provide training materials and other implementation resources to help institutions meet the new requirements and inform their research communities about the revised processes.

Thank you for the opportunity to comment.

Sincerely,

Allyssa Baptista
Biosafety Manager
Littleton, MA
allyssabaptista@gmail.com

362. Stefanie Vogel

I am responding: On behalf of myself

Name: Stefanie Vogel

Name of Organization: Univ Maryland Baltimore

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): immunology and microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: over-reaching; will create a lot of extra unnecessary oversight

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): inappropriate - current oversight is fine

3. Continued utility of Risk Groups: reporter cell lines should not be included

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Current oversight is sufficient

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Not reported well since too short a time line to comment

6. Other feedback relevant to this resource: N/A

363. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I strongly support NIH's move toward a risk-based biosafety oversight model. This is an important improvement over requirements driven primarily by the type of biological agent or research methodology. However, the proposed Policy needs to recognize more fully the interdependence of human, animal, plant, and environmental health.

Human health cannot be separated from the biological systems that sustain human life. Animal and plant diseases can threaten food production, agricultural livelihoods, ecosystem stability, and food security, with substantial consequences for human health and well-being even when the causative agents do not directly infect humans. The absence of zoonotic potential does not mean the absence of human-health consequences.

The Policy's emphasis on known or potential risk to human health should therefore account for both direct and indirect consequences. This is particularly important for non-zoonotic animal pathogens, plant pathogens, and recombinant or genetically modified organisms that may alter virulence, host range, transmissibility, or environmental persistence without creating a directly infectious hazard to humans.

I recommend that NIH explicitly adopt a One Health framework that recognizes significant risks to human, animal, plant, agricultural, and environmental health. Oversight should remain proportionate to the likelihood and severity of credible consequences rather than extending formal review to every biological activity.

Where USDA, FDA, EPA, or another federal agency has relevant jurisdiction, NIH should coordinate oversight and recognize existing regulatory determinations where appropriate. A broader understanding of biological risk should not produce unnecessary duplication or additional administrative requirements for research that presents little meaningful risk.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support the introduction of risk-based delegated IBC review, but the Policy should more clearly distinguish

institutional accountability, IBC approval authority, BSO technical authority, principal investigator responsibility, and operational implementation.

A Biological Safety Officer should lead or administer the institutional biosafety program, provide competent technical advice, and have appropriate access to institutional leadership and escalation pathways. The BSO should not, however, be expected to personally conduct every inspection, investigation, training activity, or protocol review. The Policy should expressly permit qualified biosafety personnel to perform these functions under the designated BSO's authority and oversight.

Similarly, IBC oversight should not be confused with responsibility for managing institutional operations. Emergency response, facility maintenance, incident investigation, occupational health services, and corrective-action implementation may involve different responsible institutional units. The IBC should retain its defined review and approval functions without automatically becoming the operational owner of these activities.

The Policy should also recognize qualified institutional risk assessments and decisions made in good faith using established scientific guidance. NIH should identify which decisions require prior federal approval, which may be made institutionally, and the circumstances under which NIH may require additional measures. A documented institutional risk assessment should be a defensible basis for action unless superseded by applicable requirements or subsequent NIH determinations.

Finally, where another federal agency has jurisdiction over covered research, NIH should specify whether that agency's approval substitutes for NIH review, institutional IBC review, or both. These are distinct authorities and should not be treated as interchangeable.

3. Continued utility of Risk Groups: Risk Groups remain useful for initial biological hazard characterization, but they should not independently determine laboratory containment, IBC review category, or federal approval requirements.

Risk Group classification does not account adequately for the specific experimental procedures, agent concentration and volume, routes of exposure, animal models, available engineering controls, personnel susceptibility, or the biological characteristics introduced through genetic modification. These factors must be evaluated through an activity-specific risk assessment.

The Policy should distinguish agent hazard classification from the selection of containment practices and facilities. BSL and ABSL designations describe combinations of practices, equipment, and facility safeguards and are not interchangeable with Risk Group classifications.

NIH should also reconsider the requirement to petition for containment determinations for novel, emerging, or zoonotic agents when established guidance is unavailable. A lack of an agent-specific BMBL recommendation does not necessarily mean an institution lacks sufficient expertise or evidence to make a defensible containment determination.

I recommend that NIH establish clear criteria for when federal review is necessary, permit qualified institutional review where appropriate, and publish reusable containment determinations with their

scientific rationale. Institutions should not have to submit repeated petitions for comparable work when NIH has already established an applicable precedent.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed incident-reporting requirements need clearer thresholds that distinguish events with actual or credible potential biosafety consequences from routine operational deviations and equipment failures.

In high-containment facilities, an individual component failure does not necessarily constitute a loss of containment. Facilities employ layered engineering controls, operational procedures, and redundant systems specifically to prevent individual failures from resulting in exposure or environmental release. When the required containment function remains effective, failure of one component should not automatically trigger federal incident reporting.

NIH should define incident, exposure, release, breach of containment, and loss of containment, with examples distinguishing institutional documentation, IBC review, and mandatory NIH notification. These determinations should consider the hazard involved, actual or credible exposure potential, containment performance, and consequences rather than relying solely on the facility's BSL designation.

The Policy should also define when the 24-hour reporting period begins. An initial notification should require reasonably available facts, not a completed investigation or established root cause. Institutions should be able to revise preliminary classifications as additional evidence becomes available without penalty for a reasonable, good-faith initial determination.

I am particularly concerned about mandatory public disclosure of individual incident reports. Effective incident reporting depends on workers and investigators promptly disclosing mistakes, near misses, and unexpected events. Publishing identifiable information, preliminary findings, investigator names, and potentially sensitive facility or research details can discourage reporting and create privacy and biosecurity concerns.

NIH should distinguish complete regulatory reports from public-facing summaries. Public information should explain the event, its biosafety significance, the institutional response, and corrective actions without unnecessarily identifying personnel or disclosing sensitive operational information. Deidentified or aggregated reporting may provide greater value for preventing recurrence.

Finally, institutions subject to overlapping NIH, Federal Select Agent Program, or other reporting obligations should be permitted to rely on a common factual investigation and coordinated reporting process, while satisfying applicable program-specific requirements.

6. Other feedback relevant to this resource: The proposed Policy cannot be implemented consistently until NIH has issued the substantive guidance necessary for institutions to determine what compliance requires.

I recommend that NIH publish the final Policy together with authoritative implementation documents,

including risk-assessment criteria, containment guidance, incident-classification examples, reporting instructions, and clear definitions of institutional decision-making authority. These documents should distinguish mandatory requirements from recommended practices and identify when institutions may adopt equivalent risk-based controls.

In particular, the Policy should explicitly define the requirements for BSL-3 enhanced containment and associated occupational-health programs. Requirements currently contained in the NIH Guidelines should not be transferred into later guidance without clearly identifying which provisions remain mandatory, whether any have changed, and where authoritative requirements will reside.

The proposed six-month implementation period is insufficient if institutions must also revise their IBC procedures, training, information systems, incident-reporting workflows, public-disclosure processes, and existing research classifications. These changes require institutional coordination, resources, and, in some cases, new technical competencies or personnel.

The implementation period should begin only after all material requirements and supporting resources have been released. NIH should allow phased implementation where appropriate, establish predictable review timelines, and provide institutions with sufficient opportunity to assess their research portfolios and implement sustainable compliance programs.

NIH should also evaluate its own capacity to provide timely containment determinations, Assurance approvals, policy interpretations, and other required federal reviews. Institutions cannot meet compliance obligations that depend on NIH decisions unless those decisions can be obtained within predictable timeframes.

364. Hackensack Meridian Health

I am responding: On behalf of an organization

Name: Lauren Testa

Name of Organization: Hackensack Meridian Health

Type of Organization: Healthcare Institution

Role: Other

Role - Other: Consultant

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: FINAL-HMH-NIH-Biosafety-Policy-Comments.pdf

Description: HMH supports a modernized, risk-based biosafety framework that protects research personnel and communities, clearly delineates oversight responsibilities, and avoids unnecessary duplication. NIH should concentrate its oversight on preclinical biosafety standards and novel or higher-risk activities, while the Food and Drug Administration (FDA) remains the primary federal regulator of clinical research involving advanced biotechnology products. Appropriate institutional biosafety review should address risks arising from local handling and administration without repeating FDA product review or Institutional Review Board (IRB) review of human subject protections. The final policy should translate these principles into clear scope boundaries, workable review categories, and coordinated implementation. Our recommendations below address the draft's scope, tiered oversight, risk assessment, compliance, and implementation resources. Please see the attached letter for our full comments.

HMH Hackensack Meridian Health

Via Electronic Submission - https://osp.od.nih.gov
Dr. Jay Bhattacharya
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

October 19, 2026

RE: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Dr. Bhattacharya,

On behalf of Hackensack Meridian *Health* (HMH), we thank you for the opportunity to comment on the National Institutes of Health (NIH) Draft Biosafety Policy for Research Involving Biohazards.[1]

HMH is the largest, most comprehensive, and truly integrated health care network in New Jersey, comprising a network of hospitals that includes three academic medical centers, one university teaching hospital, two children's hospitals, eight community hospitals, a behavioral health hospital, two rehabilitation hospitals and one long-term acute care hospital. Six of our 18 hospitals maintain robust academic medical programs. HMH also has more than 500 patient care locations, including ambulatory care centers, surgery centers, cancer centers, home health services, long-term care and assisted living communities, ambulance services, lifesaving air medical transportation, fitness and wellness centers, rehabilitation centers, urgent care centers, and physician practice locations. HMH has more than 40,000 team members and more than 7,000 physicians within its network and is a distinguished leader in health care philanthropy, committed to the health and well-being of the communities it serves.

As a national leader in clinical innovation and translational research, HMH has extensive experience conducting clinical trials involving advanced therapeutics, including gene and cell therapies. Operating at the intersection of clinical care and research, HMH brings direct experience implementing biosafety protocols in real-world care settings and offers a unique perspective on how federal biosafety requirements affect trial feasibility, patient access, and operational complexity.

Overview of HMH's Comments

HMH supports a modernized, risk-based biosafety framework that protects research personnel and communities, clearly delineates oversight responsibilities, and avoids unnecessary duplication. NIH should concentrate its oversight on preclinical biosafety standards and novel or higher-risk activities, while the Food and Drug Administration (FDA) remains the primary federal regulator of clinical research involving advanced biotechnology products. Appropriate institutional biosafety review should address risks arising from local handling and administration without repeating FDA product review or Institutional Review Board (IRB) review of human subject protections.

[1] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

The final policy should translate these principles into clear scope boundaries, workable review categories, and coordinated implementation. Our recommendations below address the draft's scope, tiered oversight, risk assessment, compliance, and implementation resources.

Scope and Coordination of Clinical Research Oversight

With respect to Section II, ***HMH recommends that NIH clearly distinguish preclinical laboratory research, laboratory activities supporting clinical trials, and administration of investigational products in clinical settings.*** Biosafety assessment should focus on the settings in which products are prepared, handled, and administered and the procedures performed in those settings. The final policy should explain which activities in hospital pharmacies, infusion areas, specimen-processing facilities, and clinical laboratories are covered, and distinguish research from routine diagnostic testing and clinical care. Clear boundaries are especially important for health systems in which research and care occur in shared facilities.

Section II allows research under another federal agency's purview to proceed under that agency's oversight once applicable approvals or clearances are obtained. NIH should clarify how this provision interacts with the clinical research requirements in Section IV-2. For FDA-regulated trials, HMH recommends that FDA remain the primary federal regulator and that NIH-specific requirements be limited to distinct biosafety concerns not adequately addressed through existing federal and institutional processes. FDA oversight should not automatically eliminate necessary local biosafety assessment, but institutions should be able to rely on relevant FDA-reviewed and sponsor-provided information rather than recreate it.

HMH recommends that any IBC review of clinical trials focus on local exposure and containment risks, including product preparation, administration, shedding, and waste handling, rather than reassessing clinical benefit, product efficacy, or human subject protections. Although commercial IBCs have improved the separation of these functions, explicit NIH guidance would help institutions apply these boundaries consistently. NIH should provide an explicit division of responsibilities among FDA, IRBs, Institutional Biosafety Committees (IBCs), investigators, and clinical safety personnel so that necessary reviews can proceed in parallel without duplicating their respective functions.

Risk Based Categories and Streamlined Review

HMH supports the distinction in Section IV between research requiring NIH and IBC approval, research requiring IBC approval, and lower-risk research eligible for delegated review. Federal review should concentrate on activities for which material uncertainty or higher biosafety risk requires NIH expertise. NIH should publish clear criteria and examples for assigning research to each category and provide timely determinations when federal review is required.

For Section IV-2 clinical research, NIH should clarify how the triggers of shedding, replication, integration, and higher-risk manipulation translate into biosafety risk in the specific clinical activity. HMH recommends that the final policy distinguish risks to research personnel and the community from product characteristics primarily relevant to the treated participant. For example, assessment of a viral-vector investigational product should consider whether shedding could expose household or community contacts, based on the product's characteristics and available shedding data. The

presence of an integrating component, for example, should not by itself substitute for assessment of potential exposure, transmission, and the procedures performed at the site. This distinction would help avoid imposing the same review burden on products with substantially different biosafety profiles.

HMH supports delegated review under Section IV-3 for well-characterized, lower-risk research and minor amendments. NIH should clarify whether and when FDA-regulated clinical protocols with established safety experience may qualify for delegated review after an appropriate institutional assessment. Guidance should also distinguish amendments that change the biosafety assessment from administrative changes that can be documented without a new substantive review. These pathways should preserve IBC accountability and escalation when new information identifies additional risk.

For multicenter trials using the same product and protocol, NIH should allow institutions to use common sponsor biosafety documentation and shared assessments of product characteristics, supplemented by review of each site's facilities, personnel, and procedures. HMH uses an external IBC for many multicenter trials and its local IBC for preclinical research and certain clinical projects. NIH should clarify whether centralized or externally administered IBC arrangements can support this approach and what responsibilities remain with each participating institution.

Risk Assessment and Containment Decisions

In response to NIH's question on Risk Groups and Biosafety Levels, ***HMH recommends retaining Risk Groups as an initial reference while determining containment through an assessment of the actual agent or construct, proposed manipulations, potential exposure routes, and available safeguards.*** Risk Groups and Biosafety Levels serve different purposes and should inform one another. For genetically modified materials, the assessment should account for the effects of the modification rather than assume that the parent agent's characteristics fully describe the resulting material.

NIH should provide practical examples showing how institutions should evaluate attenuation, replication competence, integration, shedding, and administration procedures, as relevant. For viral-vector therapies studied in rare genetic disease trials, examples should explain how available shedding data and potential exposure routes inform precautions for household contacts after a participant leaves the clinical site. Such guidance would make decisions more consistent while preserving institutional judgment about local facilities and personnel. NIH should also provide a clear process for applying previously published containment determinations to materially comparable research.

Consistency Across Sectors and Proportionate Compliance

HMH encourages consistent biosafety expectations for substantially similar preclinical research across academic, health system, nonprofit, and commercial settings. Because NIH funding conditions do not reach every institution conducting comparable research, NIH should promote voluntary adoption through accessible guidance, model procedures, training, and coordination with other federal agencies. NIH should recognize equivalent protections provided by other applicable oversight frameworks rather than impose duplicative processes solely to achieve formal uniformity.

For institutions subject to the policy, Section II's application beyond individual NIH-funded projects makes clarity about institutional boundaries particularly important. NIH should explain how the requirements apply to affiliated hospitals, separately incorporated entities, sponsored research, and collaborating sites, and how responsibilities should be documented. Where multiple institutions participate in the same trial, NIH should allow documentation to focus on site-specific differences from the shared product and protocol assessment, rather than require each institution to repeat that assessment. Institutions should have clear notice of their obligations and a predictable process for addressing compliance concerns. Enforcement should be proportionate to the seriousness of the violation, associated risk, and corrective action taken.

Implementation Resources and Administrative Requirements

HMH recommends that NIH issue complete implementation guidance before the compliance period begins, including a decision tool for scope and review categories, examples for FDA-regulated clinical research, model delegation procedures, and instructions for coordinating institutional and sponsor documentation. NIH should provide a transition process for existing IBC approvals and ongoing studies, and ensure that institutions can obtain Biosafety Assurance approval without unnecessary interruption of research. The implementation schedule should reflect the time needed to inventory covered research, update procedures, and train personnel.

With respect to Section III-B and the draft reporting templates, NIH should allow institutions to use existing electronic systems and equivalent formats that capture all required information. The final guidance should clearly distinguish incidents requiring prompt NIH notification, lower-risk incidents requiring institutional review, and minor events that do not require reporting. Standardized examples would help institutions meet reporting expectations consistently without diverting attention from events with meaningful safety implications.

Public reporting should communicate the nature of the biosafety risk and corrective measures while protecting patient and employee privacy, confidential sponsor information, and security-sensitive details. HMH recommends clear redaction guidance and examples for clinical research settings, including circumstances in which combinations of otherwise non-identifying facts could reveal a participant's identity. NIH should also clarify the relationship between mandatory incident reporting and voluntary confidential reporting to the National Biosafety Data and Safety Analysis Center so that institutions can support safety learning while meeting their compliance obligations.

Conclusion

HMH appreciates NIH's consideration of our comments and looks forward to continued engagement on these important issues. If you have questions, please feel free to contact me at 201-370-8279 or Sarah.Lechner@hmhn.org.

Sincerely,

[redacted]

Sarah Lechner
SVP, Chief of External Affairs

365. ADA Forsyth Institute

I am responding: On behalf of an organization

Name: Debra November-Rider

Name of Organization: ADA Forsyth Institute

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: ADA-Forsyth-Comments_NIH-Biosafety-Policy_19Oct26.pdf

Description: NIH Biosafety Policy Comments

ADA Forsyth®

To Whom it May Concern,

The unification of oversight for all research involving biohazards, whether or not such research involves recombinant or synthetic nucleic acid technology, is a positive change and one that supports a more comprehensive and cohesive institutional biosafety program. The addition of a Delegated Review mechanism is another positive change, which reduces the burden on Institutional Biosafety Committees (IBCs), while providing institutions with the flexibility to define the Delegated Review process in a way that ensures appropriate oversight of lower-risk activities at individual institutions. We support these notable policy improvements.

While many aspects of the draft Policy represent improvements, there are several changes that are likely to have significant negative consequences, as well as points that would benefit from clarification. We respectfully submit the comments below for consideration to further improve the Policy.

1. New incident reporting requirements have an expanded scope of what counts as an incident in addition to the requirement to post all incident reports on a public website.

    a. **Impact:** These changes are expected to have a significant negative impact. The trust that biosafety programs have built up over the years in supporting researchers and encouraging people to report accidents will be eroded by fear of negative ramifications and/or retaliatory action. Even if reporting is anonymized and only a PI or supervisor name is included in the published report, there is a perceived risk of that information being used against the person, lab, and/or institution. People will be less likely to report accidents, which increases the risks associated with untreated injuries or exposures to hazardous materials.

    b. **Recommendation 1**: Individual incident reports should not be publicly posted. Reporting should be to NIH, where data on incidents can be aggregated and trends analyzed and/or reported in a way that removes institutional affiliation to further anonymize individuals involved in an incident. That allows for analysis of the data and identification of trends, which would be a valuable resource to the community, while avoiding negative consequences on the individual, lab, or institution, which would, in turn, undermine the value of the incident reporting process.

    c. **Recommendation 2**: If institutions must be required to publicly post incident information, allow an aggregated annual report. Such an approach could be modeled after OSHA's Form 300A (Summary of Work-Related Injuries and Illnesses). We would

strongly recommend this approach for incidents defined by this Policy, which would not be reported to NIH but would be reported to the IBC.

2. The draft Policy states that IBC approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required. It further lists failure to maintain IBC approval as a reportable incident.

    a. **Impact:** The expected impacts of these changes are a significantly increased administrative burden and unintentional non-compliance. In the absence of a specified term limit, many institutions adopted internal policies that require IBC approval to be renewed within a 5-year period, which also coincides with the length of many grants supporting the approved research activities. Switching to a shorter 3-year renewal cycle presents a significant increase in committee workload. Additionally, well-intentioned PIs may face unexpected emergencies, or their registration renewal may come at a time when they are burdened with high workloads from teaching and/or other institutional responsibilities. Because there is no mechanism described in the draft Policy for allowing extensions to PIs facing extenuating circumstances, failure to renew an IBC registration on time would result in a reportable incident of non-compliance.

    b. **Recommendation 1:** Keep a defined term limit on IBC approval but increase the term of IBC approval to 5 years.

    c. **Recommendation 2:** Empower IBCs to exercise judgement and flexibility in granting reasonable, one-time extensions to PIs facing extenuating circumstances and/or moving a registration renewal to a different time of year so as not to conflict with other high-workload periods.

3. The draft Policy states that research with primary cells that may be contaminated by adventitious agents requires IBC review and approval under Section IV-2. We interpret this new scope to mean that any primary human cell line, tissue, or clinical specimen with an unknown status (has not been tested for bloodborne pathogens or other infectious agents) will have to go to the IBC for approval, whereas none of this material required IBC review previously. Instead, this material fell under the OSHA Bloodborne Pathogens Standard, which requires institutions to establish oversight mechanisms that have worked for many decades.

    a. **Impact**: This change is expected to have a significant negative impact. The increased burden on most IBCs will be enormous, with no apparent benefit, since the existing mechanisms to comply with the OSHA Bloodborne Pathogens Standard must still be

maintained. This is an unnecessary duplication of oversight, and the increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

b. **Recommendation**: Allow this type of material to be approved via the new Delegated Review process described in Section IV-3 rather than requiring IBC review. That would allow institutions flexibility to integrate existing biosafety oversight mechanisms into the Delegated Review process defined by the new Policy.

4. The draft Policy states that research involving genetically modified cells, viruses, or organisms, other than plants requires IBC approval and approval under Section IV-2. Previously, a large portion of genetically modified cell lines were considered exempt under Section III-F-8, Appendix C-I. For many IBCs, that type of material made up the majority of genetically modified material, and because it was considered exempt and did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely and in accordance with the OSHA Bloodborne Pathogens Standard. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8, Appendix C-I now falls under Section IV-2 and requires full committee review.

   a. **Impact**: This change is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because the main risk associated with material that fell under Section III-F-8, Appendix C-I was the risk of adventitious agents or bloodborne pathogens, as mentioned in point 3 above. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

   b. **Recommendation**: Retain the Section III-F-8, Appendix C-I exemption, or allow materials that would have fallen under Section III-F-8, Appendix C-I to be approved via the Delegated Review process described in Section IV-3.

5. The draft Policy's definition of a genetic modification includes introduction into cells, organisms, or viruses of stable alterations into the genome by passaging. It is not clear what passaging activity falls within the Policy scope. Simply culturing an organism in vitro will lead to accumulation of undefined genetic alterations and could be considered passaging. Cultures that are maintained in a lab are also considered to be passaged through the process of sub-culturing to create multiple stocks from an original sample. Further, most of the time, growing an organism in vitro or in a model system selects for mutations that optimize growth in a lab environment, not in a human host, and these lab-adapted strains typically lose virulence or pathogenicity. The Influenza A/Puerto Rico/8/1934 (H1N1) strain (often called PR8 influenza) is

a classic, mouse-adapted laboratory strain of the influenza A virus isolated from a human patient in Puerto Rico in 1934. It is an example of a strain that is a lower risk option for studying influenza. These examples of passaging generally have not required IBC review. In the draft Policy, all of these activities would require IBC review and approval under Section IV-2 (see also point 4 above).

   a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because most passaging does not increase the risk of the agent or associated research activities. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

   b. **Recommendation**: We recommend refining the scope of the definition of genetic modifications by defining passaging as the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile. Examples of passaging activities that should be included in Section IV-2 include passaging with the intent or likelihood for an agent to acquire a new virulence trait or antibiotic resistance or to adapt a pathogen to a new host species and/or tissue tropism.

6. In the draft Policy, the definition of genetic modification that falls within the scope of the policy now includes modification via chemical or radiological means. Further, the draft Policy requires the IBC to review all genetically modified cells under Section IV-2 (see also point 4 above). The main risk associated with use of chemical or radiological agents to create mutations is in the handling of the chemical or radiological material, not necessarily in handling the cells once the mutagen has been removed. There are separate regulations that apply to chemical and radiological hazards. The use of chemical and radiological hazards is best handled by the respective safety experts who are familiar with the appropriate regulations and safety requirements, not the IBC. Assessment of the risks of these mutagens are outside of the scope of an IBC, since IBC members typically have little to no expertise on chemical or radiological hazards.

   a. **Impact**: This is a vast expansion of scope that will duplicate oversight and increase burden on IBCs, without a clear benefit. Further, the IBCs typically lack appropriate expertise for evaluating the risks associated with these mutagens. The increased burden on IBCs will detract attention from higher-risk matters, which do fall within the expertise of the committee.

b. **Recommendation**: Remove chemical and radiological means from the definition of genetic modifications that fall within the scope of the policy and defer oversight to existing regulations that apply to the use of chemical and radiological hazards. Alternatively, refine the scope to apply to experiments in which the mutagenic agent is combined with the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile, as recommended for passaging in point 5 above.

7. The draft policy states that research with genetically modified RG1 biological agents requires Delegated Review under Section IV-3. Previously, most standard cloning and/or protein expression with *E. coli* and other model host-vector systems were considered exempt under Section III-F-8, and it did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely with proper waste disposal procedures. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8 now requires Delegated Review.

    a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. The increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

    b. **Recommendation 1**: We strongly recommend retaining existing III-F-1 through III-F-8 exemptions.

    c. **Recommendation 2**: Furthermore, and supported by decades of safe research experience, we also recommend expanding the exemptions to include other low-risk cloning and protein expression research in model organisms such as *E. coli* BL21 strains, *C. elegans*, and *Drosophila*.

8. The draft Policy states that research conducted with transgenic organisms at BSL-1/ABSL-1" requires Delegated Review. Previously, almost all breeding or purchasing of transgenic rodents was exempt under Section III-F-8, Appendix C-VII and was not typically registered with an IBC at all. Instead, oversight of those transgenic rodents typically has been handled through federally mandated Institutional Animal Care and Use Committees (IACUCs) that have biosafety professionals as members who conduct risk assessments and suggest risk mitigation measures as part of that review process. Many IBCs do not even have a mechanism for tracking this information. Additionally, many researchers using transgenic mice are not using any other sort of biological material; the research is often focused on behavioral studies or pre-clinical studies

that fall outside the scope of an IBC. A very large proportion of transgenic animal work is done with transgenic rodents and zebrafish, and almost all of that work poses no new risk compared to the unmodified rodents and zebrafish.

a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. Again, the increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

b. **Recommendation 1**: We strongly recommend retaining the III-F-8, Appendix C-VII exemption and allow existing oversight of these low-risk animals to continue via the IACUC.

c. **Recommendation 2**: As mentioned in point 7 above, we also recommend expanding the exemptions to include other low-risk transgenic model organisms such as zebrafish, *C. elegans* and *Drosophila*.

9. The draft Policy defines biological agents that fall within the scope as bacteria, viruses, fungi, or parasites that cause human disease. This definition seems to contradict the draft Policy's requirement for Delegated Review of research with genetically modified RG1 biological agents (see point 7 above). Risk Group 1 agents are <u>not</u> associated with disease in healthy adult humans. Some agents may be considered opportunistic pathogens, but there is currently no list of RG1 organisms that are considered opportunistic pathogens.

    a. **Recommendation 1:** NIH should clarify the nature of biological agents that fall within the scope of the Policy. We recommend that the Policy scope is limited to pathogenic biological agents that cause disease in humans, including opportunistic pathogens but <u>excluding</u> non-pathogenic agents.

    b. **Recommendation 2**: As there is no list of RG1 agents, and the list of RG2 agents is incomplete, we further recommend empowering the IBCs, Biosafety programs, and PIs to make the determination of RG1 and RG2 for biological agents that are not currently listed in Appendix B of the NIH Guidelines or the BMBL using the risk assessment guidance provided therein.

10. The draft Policy's definition of a genetic modification includes introduction of materials that can be transcribed or translated. This would include materials such as purified or synthetic miRNAs, snRNAs, shRNAs, and mRNAs, which are transient in nature and may lead to changes in gene expression but do not replicate and do not modify or integrate into the genome. Work with

such materials was previously exempted under III-F-1 but would now fall under Section IV-2 and require IBC review and approval.

a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create a significant new burden on IBCs, with no apparent benefit given that no genetic modifications are made with these materials. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

b. **Recommendation:** We recommend retaining the III-F-1 exemption and removing these materials from the scope of the Policy.

11. The scope of the draft Policy includes prions and self-aggregating proteins, and research activities involving these materials would require IBC review and approval. We support the draft Policy as it pertains to prions, but request refinement of the oversight pertaining to self-aggregating proteins. IBC oversight should not extend automatically to every protein capable of self-aggregation. Protein aggregation is common in biology and, by itself, does not establish an infectious or exposure hazard. Oversight should instead focus on proteins or protein assemblies for which there is credible evidence that an aggregated conformer can act as a persistent, self-propagating seed; induce conformational conversion of the corresponding native protein; spread between cells or tissues; and transmit pathology following experimental exposure or inoculation. We recommend the following risk-assessment approach, which is consistent with the BMBL principle that containment decisions should be protocol-driven rather than based only on an agent's name.

a. **Recommendation 1:** Classical mammalian prions and prion-containing tissues should remain categorically within IBC purview because of their established infectivity, potential for serious disease, environmental persistence, and resistance to conventional inactivation procedures.

b. **Recommendation 2:** Seed-competent aggregates of α-synuclein, including preformed fibrils, amplified seeds, and α-synuclein-containing material derived from affected human or animal tissue, should also be subject to IBC review because α-synuclein assemblies have demonstrated prion-like templating, cellular and anatomical propagation, and experimental transmissibility in animal models. Inclusion under IBC oversight should not be understood to mean that α-synuclein is known to be naturally communicable between people or that it presents the same level of hazard as a classical prion.

c. **Recommendation 3:** Other self-aggregating proteins should be evaluated individually rather than be included in Section IV-2 of the draft Policy solely because they form oligomers, fibrils, or amyloid. Relevant considerations should include evidence of experimentally transmissible pathology, persistence of seeding activity, resistance to standard decontamination, source and concentration of the material, route and scale of exposure, use of human- or animal-derived pathological tissue, and procedures involving inoculation, sharps, aerosols, or other opportunities for occupational exposure. Routine work with non-seed-competent monomeric proteins or aggregates lacking evidence of biological propagation would not ordinarily require specialized biosafety review beyond the requirements otherwise applicable to the experimental system, and we recommend that the Delegated Review mechanism described in Section IV-3 be applied to such work.

12. The scope of the draft Policy includes toxins listed as Select Agents, and research activities involving these materials would require IBC review and approval under Section IV-2, while research with biological toxin proteins not on the Select Agent list may be approved by Delegated Review under Section IV-3. We support this overall approach; however, we request refinement of the Policy with the following recommendations.

    a. **Recommendation 1:** Allow research activities using exempt amounts of Select Agent toxins to be approved by Delegated Review. Most institutions have already developed effective internal biosafety oversight mechanisms for handling these exempted materials. Integrating those internal oversight mechanisms into the Delegated Review process would allow IBCs to focus on the higher-risk Select Agent work.

    b. **Recommendation 2:** Either publish a list of biological toxins that fall within the scope of the Policy or use a threshold toxicity value as a risk-based factor for determining whether a biological toxin requires oversight by the Policy. We further recommend that biological toxins that have an LD_{50} greater than 1000 µg/kg be exempt from this Policy.

13. The scope of the draft Policy includes cells, viruses, or organisms, other than plants, that have been genetically modified. It is assumed that animals are included as organisms, but it is not clear what is considered an animal under this Policy.

    a. **Recommendation:** Use a definition of animal that is consistent with the Guide for the Care and Use of Laboratory Animals, which has been adopted by the NIH Office of Laboratory Animal Welfare, and which defines animals as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

14. The draft Policy indicates that the effective date will be 6 months from publication of final Policy, and that applicability includes ongoing work. It is unclear how ongoing work will be impacted by the new review and approval requirements. Work that was not subject to IBC oversight according to the NIH Guidelines may have been approved via voluntary institutional biosafety oversight mechanisms.

    a. **Impact:** Work that was approved by a Biosafety Officer (or other institutional biosafety oversight) and now requires a higher level of review by the IBC would need to cease until IBC approval is obtained. This would have a significant negative impact on a large number of projects that are suddenly subject to new oversight, thereby wasting grant money and setting back important research projects.

    b. **Recommendation:** Require activities that have not received approval by a Biosafety Officer or other institutional biosafety oversight mechanism to be reviewed and approved according to the final Policy within 6 months of the publication of the final Policy. For activities that have received approval by a Biosafety Officer or other institutional biosafety oversight mechanism, allow the existing approval to remain in place until such time as de novo registration is required (see point 2 regarding our recommendation to allow 5-year term limits for IBC registration approvals).

Respectfully Submitted,



Xuesong He, PhD, DDS
AFI IBC Chair

366. Infectious Diseases Society of America (IDSA)

I am responding: On behalf of an organization

Name:

Name of Organization: Infectious Diseases Society of America (IDSA)

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Diseases and HIV Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We appreciate that the new policy expands to include emerging threats like synthetic biology. However, we believe the second inclusion to the policy's scope, "Cells, viruses, or organisms, other than plants, that have been genetically modified," should be further narrowed considering the policy encompasses all biomedical research in all laboratories. This is a very broad definition that could end up including incredibly basic research without dual use or major biosafety concerns. We recommend narrowing this definition – one possible option would be refining the language to target research of concern, such as: "Cells, viruses, or organisms, other than plants, that have been genetically modified to enhance an existing quality, add a novel quality, or increase transmissibility of the cell, virus, or organism."

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): We agree with NIH's intent for this policy to apply to all NIH-funded research and institutions involving moderate- or high-concern biohazards. Biosafety practices must be enforced at both the federal and local levels. However, we stress that NIH must be sure it is able to have an adequate workforce to ensure compliance work within the agency to ensure the institutions and research at the local level are complying with the policy. This policy will entail increased enforcement at both the federal and local/institutional levels, especially for research under Section IV-1, "Research That Requires NIH and IBC Approval Before Initiation," which will mean an increase in administrative work for approval, review and oversight processes. Any additional funding from NIH that could be provided to institutions to support the needed staffing for oversight and review capacity would help incentivize compliance at federally funded institutions.

3. Continued utility of Risk Groups: We agree with the continued use of the risk groups as a baseline – however, we do believe some of the definitions should be modified to make the lower-tier risk groups less broad. As it stands, the language in Section IV-2 for research "requiring full Institutional Biosafety Committee (IBC) review and approval before initiation" would expand and make many basic laboratory protocols with non-modified bacteria require institutional IBC protocol approvals, which would likely require months of wait time based on the backlog that currently exists at many institutions. For example, one specific provision includes "research involving genetically modified cells, viruses, or organisms, other

than plants." This represents a massive array of experiments and protocols that would require approval, despite the definition being so broad that many non-hazardous experiments would fall within this category. Expanding the definitions unduly to include research with low concern will only increase IBC backlogs, delay research and make it impossible to finish within defined timelines. We recommend narrowing this specific section of the policy in line with other language under Section IV-2 that specifically highlights research with reasonable hazards.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Clear, consistent, non-punitive guidance and materials from NIH will help ensure that non-NIH funded institutions still work with NIH on their biosafety policies. Many institutions do not have the staff to do consistent additional administrative work, including on biosafety reporting and review – anything that NIH can provide these institutions as templates or guidelines to help streamline that work would likely accommodate voluntary compliance.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

367. Steve Rupkey

I am responding: On behalf of myself

Name: Steve Rupkey

Name of Organization: Argonne National Laboratory

Type of Organization: Other

Type of Organization - Other: DOE Contracted R&D Laboratory

Role: Other

Role - Other: Biological Safety Program Manager

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Liquid Biological Waste Treatment with sodium Hypochlorite

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Yes, continue to use RG as a baseline for risk assessments.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Recommendation: Establish Standardized Sodium Hypochlorite Concentrations for Liquid Biological Waste Disinfection

Proposed Action

The NIH should provide specific, standardized concentrations of sodium hypochlorite (bleach) and contact times for the disinfection of Risk Group 1 (RG1) and Risk Group 2 (RG2) liquid biological waste (LBW). Specifically, the NIH should adopt and publish clear, baseline guidance such as:
• 5,000 ppm free chlorine for 20 minutes when minimal or no organic materials are present.
• 10,000 ppm free chlorine for 30 minutes when significant organic materials are present.

Justification and Problem Statement

Currently, institutions face regulatory and practical gaps when determining liquid waste treatment protocols:

• Testing is Impractical: Expecting individual research institutions to conduct independent efficacy testing for every unique RG1 or RG2 biological agent in liquid solution is logistically impractical, cost-prohibitive, and contrary to standard institutional practices.
• EPA Registration Gap: While the US EPA registers disinfectants, these approvals are almost exclusively validated for hard, non-porous surfaces, leaving a regulatory vacuum for the treatment of bulk liquids.
• Standardized Consensus Exists: Literature reviews and AI-assisted data aggregation show that 5,000 ppm and 10,000 ppm are already the most widely accepted and empirically cited benchmarks for safely inactivating RG1 and RG2 waste when no chemically incompatible agents are present.

Benefits of Implementation

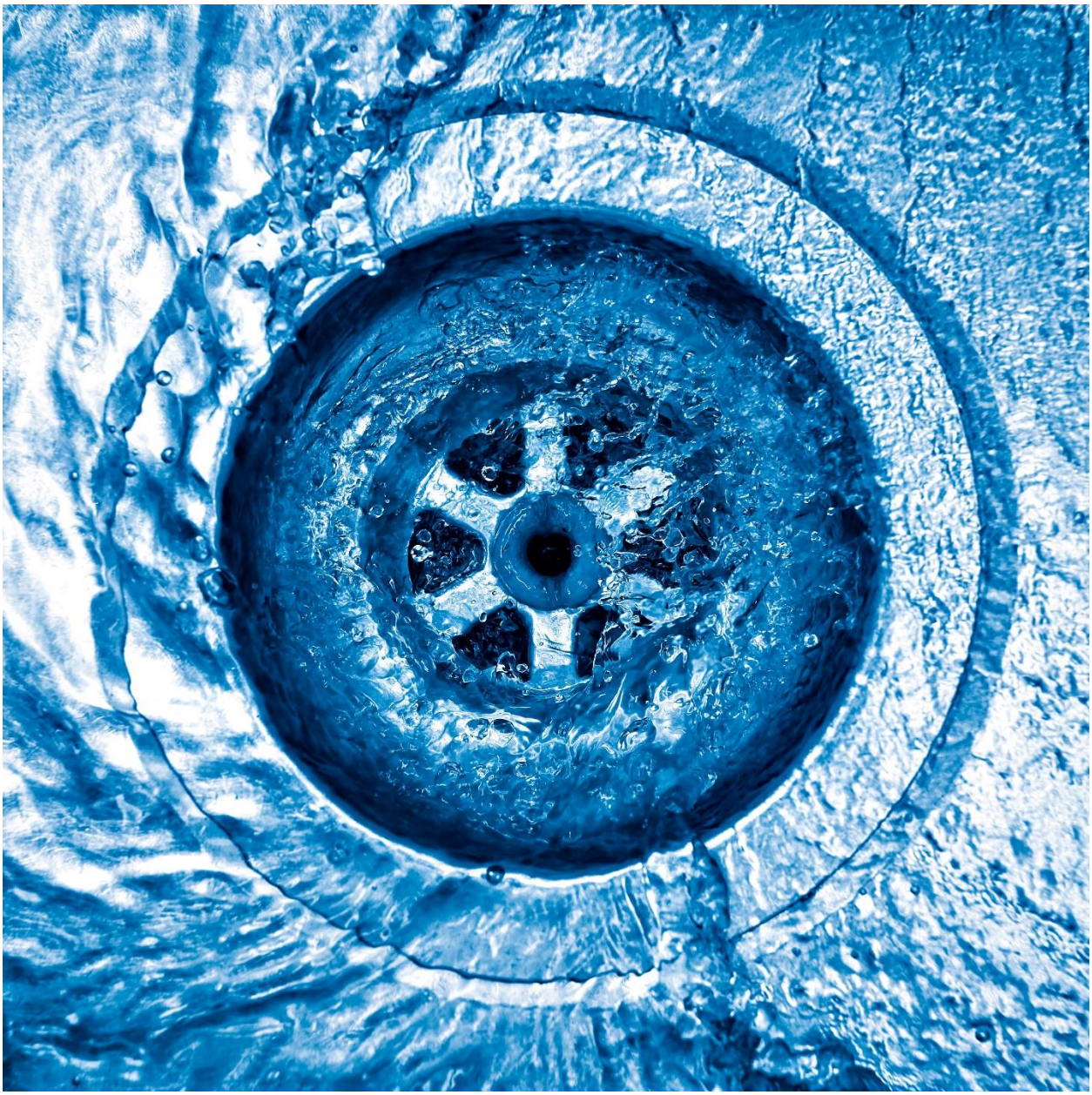
Implementing this standardized guidance will provide significant advantages across the research community:
• Enhanced Biosafety Compliance: Clear, authoritative benchmarks from the NIH eliminate guesswork, ensuring that institutions consistently achieve complete pathogen inactivation.
• Increased Operational Efficiency: Eliminating the perceived or literal requirement for individual validation testing saves institutions hundreds of hours in administrative and laboratory labor.
• Standardized Oversight: Institutional Biosafety Committees (IBCs) and biosafety officers will have a concrete, NIH-validated metric to reference during protocols reviews and facility audits.
• Reduction in Environmental/Safety Risks: Providing exact numbers prevents the common issue of over-bleaching (which creates unnecessary toxic vapors and hazardous chemical waste) or under-bleaching (which risks environmental release of viable pathogens).

Uploaded File: NIH_Drain_Discharge_Guide.pdf

Description: NIH guide on treating RG1 and RG2 materials using sodium hypochlorite in NIH laboratories.

National Institutes of Health

NIH DRAIN DISCHARGE GUIDE



NIH, **September** 2020

NIH Drain Discharge Guide, Version 1, September 2020

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OVERVIEW

The National Institutes of Health (NIH) is made up of 27 Institutes and Centers, each with a specific research agenda, focusing on diseases or body system. The NIH has over 3000 labs on the Bethesda campus, including local off-campus and regional facilities, where biomedical research is conducted including animal facilities, clinical and patient care areas and industrial activities. These activities produce an array of waste both hazardous and nonhazardous which must be managed appropriately. This document provides guidance based on policy, permits, and regulations, for materials which must be collected for proper disposal and a select group of chemicals which can be discharged under specific conditions. The NIH objective is to dispose of chemicals via the waste management service and limit discharges to the sanitary sewer. Current NIH waste management practices include collection of chemicals through waste disposal services. **Only chemicals pre-approved for drain disposal** may be disposed of down the drain (see page 3). All other chemical waste should be managed and disposed of as chemical waste according to the instructions on page 3 of this guide. The NIH will review policies, regulations and procedures, and update this guide on a periodic basis.

WASTE POLICY

The NIH waste policy requires that all wastes be reduced to the greatest extent feasible to limit any negative environmental impact. Proper management of all wastes, including their characterization, collection, labeling, packaging, storage, recycling, transportation, treatment and final disposal, is also required. Disposal of chemical wastes, including pharmaceutical wastes, via the sanitary sewer is regulated by federal, state and local laws and regulations. Violation of these regulations may result in citations for non-compliance from local, state or federal authorities.

Per EPA regulations, wastes are considered hazardous if they exhibit any of the following characteristics: ignitability, corrosivity, reactivity, and toxicity; or if they are specifically named on one of four lists of hazardous wastes in the Code of Federal Regulations (40 CFR). Additional state and local laws and regulations also apply respectively to waste generated in NIH facilities. These regulations and restrictions must be adhered to by all NIH personnel, contractors and/or anyone involved with the generation of wastes or waste management and support services at all NIH facilities, including but not limited to the Bethesda main campus, local off-campus facilities (Baltimore, Frederick, Poolesville and Rockville) and regional facilities (Montana and North Carolina).

CHEMICALS APPROVED FOR DRAIN DISPOSAL

It is the responsibility of each NIH laboratory worker to ensure that chemical waste generated from their activities is disposed of properly. Chemicals put down the drain may interfere with the process of removing contaminants from Publicly Owned Treatment Works (POTW). After treated waste water leaves the POTW, it flows to major recreational and drinking water resources in our areas. The stewardship of these important natural resources is our collective responsibility.

Laboratory workers should consult this guide before undertaking drain disposal of any lab chemicals. **Only chemical approved for drain disposal** by the NIH Division of Environmental Protection (NIH/DEP) may be disposed of down the drain. **Surplus solid chemicals must be disposed of through the NIH chemical waste services and not discharged down the sanitary sewer**. Below is the approved chemicals list. Click A – Z to expand the list for approved chemicals or see the Expanded List at the end of this Guide (see Appendix B).
Chemicals that are not listed below must be managed as chemical waste and collected by your IC's chemical waste service for disposal (see Appendix A). Dilution to achieve compliance is prohibited per EPA CFR Dilution Prohibition.

When disposing of approved chemical via the drain use the following procedure:

1. *Ensure the sink to be used for drain disposal of chemicals is clear of all items.*
2. *The worker shall wear appropriate PPE (lab coat, nitrile gloves, and protective eye wear).*
3. *Turn on cold water and let run for about one (1) minute to ensure there is adequate flow of water down drain, no back up into the sink. Do not use the sink for disposal of chemicals if water does not freely flow down the drain.*
4. *Slowly pour material down the sink drain minimizing splashing.*
5. *Rinse out the material container if to dispose of, recycle, or reuse.*
6. *Clean sink to ensure sink basin is free of material.*
7. *Let tap water run for about two (2) minutes after pour to allow the material to flush through p-traps.*
8. *Shut off water taps to sink.*

CHEMICAL DETERMINATION FOR HAZARDOUS WASTE

If the chemical in question is not already on the "Chemicals Approved for Drain Disposal" list (see Appendix B), the NIH will need to determine if it is acceptable for disposal. **Generally, if the chemical waste is Ignitable, an Oxidizer, Corrosive, Reactive or Toxic, it is a hazardous waste that needs to be collected for disposal. Additionally, chemicals on EPA waste lists F, K, P, and U are identified as hazardous waste and subject to disposal regulations**. EPA periodically updates the CFR Title 40 – Protection of Environment, Volume 27, Part 261 – Identification and Listing of Hazardous Waste.

Chemical wastes that are already listed on the "Chemicals Approved for Drain Disposal" list (see Appendix B) are approved for disposal down the drain when not mixed with unapproved materials. If a chemical waste that is generated in your lab, does not appear on the list, you can request standing approval for drain disposal at DEP's Application for Disposal of Specific Chemical Reagents to the Sanitary Sewer. System wastes, disinfection wastes, or chemicals associated with disapproved mixtures will be approved on a case-by-case basis. If approved, the chemical will be added by DEP to the list of Chemicals Approved for Drain Disposal. If disapproved, collect as chemical waste and request pickup through waste disposal authority (see Appendix A).



WASTE CONTAINING ANTIBIOTICS

NIH is committed to avoiding the release of antibiotics that can reach the ecosystem. Autoclaving is the best practice and reliable means to inactivate antibiotics. Antibiotic waste must be treated differently depending on its stability. Request discharge to drain, with inactivation by other methods, requires an approval at DEP's Application for Disposal of Specific Chemical Reagents to the Sanitary Sewer.

Inactivate by heat (autoclave or boil) before pouring down the drain	Must be submitted for combustion (treated as **hazardous waste**)
Ampicillin	Blasticidin-S
Amphotericin B (Fungizone)	Choramphenicol
Carbenicillin	Ciprofloxacin
Erythromycin	Enrofloxacin
Geneticin (G418)	Kanamycin
Gentamicin	Nalidixic acid
Neomycin	Vancomycin
Penicillin	Zeocin
Puromycin	Zeomycin
Streptomycin	
Sulfadoxine	
Tetracycline	

Antibiotics not listed above should be collected as chemical waste. See waste services disposal guide for additional information.

LIQUID BIOHAZARDOUS WASTE DISPOSAL

Proper biohazardous waste treatment is important to ensure sterilization or deactivation prior to disposal. Biohazardous wastes consist of microbial cultures, viruses or recombinant DNA. Biosafety Risk Groups are designated 1 (agents with little risk to an individual or community) to 4 (agents with the highest risk to an individual or community). In this guide, only Risk Groups 1 and 2, with approval, will be considered for drain disposal. Risk Group 1 agents represent little to no risk to an individual or community. Risk Group 2 represents moderate risk to an individual but no risk to a community. Risk Groups 3 and 4 should be collected as Medical Pathological Waste (MPW). Risk Group 3 agents are serious or lethal human disease for which preventive or therapeutic interventions may be available. Risk Group 4 agents cause serious or lethal human disease without preventive or therapeutic interventions available. For more information, see DHHS's Biosafety Risk Groups. Biohazardous waste containing chemicals or radioactive waste should be collected for disposal through the appropriate waste management service

Below are the steps necessary for drain disposal of Risk Group 1 and 2 biohazardous wastes:

1. Wear appropriate PPE such as gloves, lab coat and eye protection when working with biohazardous waste
2. A bleach mixture (final concentration of 1:10 or 10%) for a contact time of a minimum of 20 minutes should be used to decontaminate biohazardous liquids. Once the liquid has been decontaminated, it can be poured down the drain. If using another disinfectant such as alcohol-based or Wescodyne® for decontamination, direct to the waste disposal guide for the appropriate disposal method.

NANOMATERIAL-CONTAINING WASTE

Chemical wastes containing nanoparticles shall not be disposed of as regular waste or poured down the drain (refer to the NIH Nanotechnology Safety and Health Program, 9.0 Waste, pages 7-8). Contact the waste management service for additional assistance with disposal recommendations for all nanomaterial related waste.

PHARMACEUTICAL WASTE

Hazardous pharmaceutical wastes governed by regulations under the Resource Conservation and Recovery Act (RCRA). Pharmaceuticals entering the environment via drain disposal have the potential to negatively impact aquatic ecosystems, including fish and animal populations, and can lead to water contamination and other public safety concerns. **Any pharmaceutical waste must be handled as chemical waste**. Pharmaceutical wastes are drugs, vaccines, and anti-neoplastic drugs; including contaminated pharmaceutical products and equipment. The acquisition, use and disposal of controlled substances at NIH is subject to strict Federal Drug Enforcement Administration (DEA) and State Department of Justice regulations. These regulations and directives set specific requirements and restrictions on registration, acquisition, usage, record keeping, transfer, storage and disposal.

Individuals who manufacture, distribute, dispense, import, export, conduct research or perform chemical analysis with any controlled substances including precursor chemicals are subject to a DEA registration.

REFERENCE LIST

Waste Policy

3032 – Environmental Management and Waste Minimization at the NIH, https://policymanual.nih.gov/3032 (NIH/DEP, Apr 2019, retrieved on Jun 27, 2019)

3033 - Procurement, Use and Disposal of Mercury and Its Compounds, https://policymanual.nih.gov/3033 (OD/OM/ORFDO/DEP, May 2014)

Chemicals Approved for Drain Disposal

EPA CFR Dilution Prohibition https://www.ecfr.gov/cgi-bin/text-idx?SID=95d8417912f93e3e920333baef3bebff&mc=true&node=se40.27.268_13&rgn=div8 (EPA, May 1998, retrieved on Jun 26, 2019)

Chemical Determination for Hazardous Waste

NIH/DEP Application for Disposal of Specific Chemical Reagents to the Sanitary Sewer https://spapps.od.nih.gov/sites/DEPAuthorizations/SitePages/Home.aspx (NIH/DEP, retrieved on Jun 26, 2019)

NIH Waste Disposal Guide (2014) https://www.orf.od.nih.gov/EnvironmentalProtection/WasteDisposal/Documents/2014WasteGuide508-09302015.pdf (NIH/OM, 2014, retrieved on Jun 26, 2019)

APPENDIX A – NIH ICS CHEMICAL WASTE DISPOSAL CONTACTS LIST

NIH

NIH/ORF/Waste Management Services
https://www.orf.od.nih.gov/EnvironmentalProtection/WasteDisposal/Pages/default.aspx

For questions and help, contact your Safety and Health Specialist,
NIH/OM/SOSB/DOHS,
https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/Pages/safety_health_specialists.aspx

NIH at Baltimore
https://nems.nih.gov/Documents/NIA%20Waste%20Guide.pdf

Montana
Hamilton
https://nems.nih.gov/NEMS-locations/Pages/NIAID_at_Rocky_Mountain_Laboratories_Montana.aspx

North Carolina
Research Triangle Park
https://apps.niehs.nih.gov/hsb/pickups/

NCI at Frederick
Fort Detrick
https://ncifrederick.cancer.gov/Ehs/WasteManagement/

APPENDIX B – EXPANDED LIST OF CHEMICAL SOLUTIONS APPROVED FOR DRAIN DISPOSAL

Note: (*) = allowable concentration limit (•) = antibiotic

A

A-Glucosidase, Type I
*Acetic Acid (≤10% with pH > 6)
Albumin, Bovine (without Sodium azide)
Albumin, Serum (Human) (without Sodium azide)
Alconox (≤1%) (10 g/L)
Alpha-D (+) Melibiose
•Amphotericin B (Fungizone) (Autoclave, pg. 5)
•Ampicillin (Autoclave, pg. 5)
*Animal Drinking Water (≤4% Deuterated Water)
Artificial Cerebrospinal Fluid (aCSF) (NaCl, $MgSO_4$, KCl, KH_2PO_4, Dextrose, $NaHCO_3$, $CaCl_2$, Kynureic Acid)

B

B-D (+) Glucose, and all Isomers – Beta D Glucose
Bacto Tryptic Soy Broth
Basal Medium Eagle
BD™ FACSFlow™ Sheath Fluid
Beta-Glucuronidase, Type VIII
Bicine [N, N-bis (2-hydroxyethyl) glycine]
Bile Salts
*Bleach (≤10% Clorox Bleach)
Blood Bank Saline
Bovine Serum Albumin (BSA)
Brain Slicing Perfusion Solution

C

Calcium Bicarbonate
Calcium Carbonate
Calcium Chloride
Calcium Citrate
Calcium Phosphate, Monobasic
Calcium Sulfate
•Carbenicillin (Autoclave, pg. 5)
Carboxypeptidase B
Carboxypeptidase Y

Carrageenan, Type II
Casein
Cellulase, all types
Chitin
Chondroitin
Chymotrypsinogen
Click's Medium
CM Cellulose Powder
Cocarboxylase
Coenzyme A, Sodium Salt
Collagen & Collagenase
Complete Dulbecco's Modified Eagle's Media (DMEM-C)
Cytidine 2' & 3' - Monophosphates
Cytidine 2' & 3' – Triphosphates
Cytosin

D

2' DeoxyAdenosine 5' Triphosphate
2-Deoxy-D-Ribose
D-Broth (Dehydraged Broth) (≤1% Sodium chloride)
D-Cellobiose
D-Erythrose
D-Fructose and other Isomers & Enzymes
D-Glycogen
D- (+) Maltose, Monohydrate
D-Ribose 5-Phosphate, Disodium Salt
D-Sorbitol
D-Xylose
Deoxyribonucleic Acid, Type XV
Dextran
Dextrose
*Dialysis Buffer for Protein Purification [(20mM Tris-HCl, 100mM Urea) with removal of DDT, BME, or preservatives]
*Diethylene Triamine Penta Acetic Acid (DTPA) (<10 mM with pH≤6)
Disodium Phosphate
*Dithiothreitol (DTT) (≤1 M)
DL-Cystine
DL-Histine
DL-Homoserine
DL-Isoleucine
DL-Leucine
DL-Serine
DL-Threonine

DNA Polymerase I
*Donkey Serum, Normal (≤5%)without Sodium Azide]
Dulbecco's Modified Eagle's Medium (DMEM)
Dulbecco's Modified Eagle Medium (DMEM), without Phenol Red
Dulbecco's Modified Eagle Medium (DMEM), with Phenol Red
Dulbecco's Modified Eagle's Medium (DMEM)/Ham's Nutrient Mixture F-12
Dulbecco's Modified Eagle Medium (DMEM), High Glucose, Pyruvate without Phenol Red
Dulbecco's Modified Eagle Medium (DMEM) High Glucose
Dulbecco's Modified Eagle Medium/Nutrient Mixture F-12 (DMEM/F12), without Phenol Red
Dulbecco's Modified Eagle Medium/Nutrient Mixture F-12 (DMEM/F12), with Phenol Red

E

Eagle's Minimum Essential Medium (EMEM)
Earl's Balanced Salt Solution (EBSS)
Elastase Type III
EmbryoMax® Advanced KSOM Medium
Enolase
Epidermal Growth Factor, Human (hEGF)
•Erythromycin (Autoclave, pg. 5)
Essential 6 Medium
*Ethanol (≤10% with a Flash Point >140°F)
*Ethylenediaminetetraacetic Acid (EDTA) (≤10 mM)
*Ethylene Glycol Tetraacetic Acid (EGTA) (≤10 mM)

F

F-12 Coon's Modification Formulation
Fetal Bovine Serum (FBS)
Fetal Bovine Serum Charcoal Stripped
Fetal Calf Serum (FCS) (FCS)
Fibrinogen
Fibronectin
Fischer's Medium
Flavin Adenine Dinucleotide
Folic Acid
Fructose

G

Galactose
Gelatin

•Geneticin (G418) (G418) (Autoclave, pg. 5)
•Gentamicin (Autoclave, pg. 5)
Gibberellic Acid (GA)
Glasgow Minimum Essential Media
Glucose
Glucose Enzymes & Phosphates (All)
Glutamax
Glutamic Acid (including D, L, DL Isomers)
*Glutamine Autoclave Prior to Disposal)
Glycine
GlycylGlycine
Grace's Insect Medium
Guanosine 3', 5' Cyclic Monophosphate

H

Ham's F-12 Medium (F-12)
Hank's Balanced Salt Solution (HBSS)
Hemoglobin
HEPES (N-2-hydroxyethylpiperazine-N-2-ethane sulfonic acid) Buffer
HEPES-Buffered Saline
Hexokinase
Histone
Human Basic Fibroblast Growth Factor (hFGF basic/hFGF-B)
Hyaluronidase Type I-S
*Hydrogen Peroxide (≤8%)

I

Immunoglobulins, IgG
Immunoglobulins, IgM
Immunoglobulins, IgE
Insect Medium Supplement
Instant Ocean® Sea Salt
Insulin
Invertase,Grade V
IPL-41 Insect Medium
Iscove's Modified Dulbecco's Medium IMDM)
IsoFlow™ Sheath Fluid (Beckman Coulter)
*Isopropanol (2-propanol) (<2% with Flash Point >140°F)

J

Joklik's Minimum Essential Medium Eagle

K

Krebs-Henseleit Buffer

L

L-Citrulline
L-Glutamine
L-15 Media
L-Proline
L-Serine
L-Sorbose
L-Threonine
L-Valine
Lactic Dehydrogenase (including D-isomer)
Lactoferrin, Globulin, alpha-Lactose
Lactose
Lectin
Lectin from Glycine Max
Leibovitz's L-15 Medium
Lithium Acetate
Litmus Milk Medium
Lithium Carbonate
*Lithium Chloride (≤1%)
*Lithium Sulfate (≤1%)
Luria Broth (LB)
Lysozyme, Grade I

M

M2 Medium
M9 Minimal Medium
M9 Minimal Salts
M16 Medium
Magnesium Chloride (≤1%)
Magnesium Sulfate (≤1%)
Maltose
McCoy's 5A Modified Medium
MCDB Medium
Medium 199
*MEM Amino Acids (1X)(pH >6 and <9)
*MEM Vitamin Solution (1X)
Methylcellulose (Paraben)
*Methylene Blue Embryo Water (Zebrafish only, 2ml of 0.1% methylene blue)
Milk (Non-fat dry)

Minimum Essential Medium Eagle (MEM)
Modified Ringer's "Artificial Cerebrospinal Fluid" Solution
Monopotassium Phosphate

N

Nicotinamide Adenosine Diphosphate (NADP)
NCTC Medium
Nematode Medium (Axenic)
•Neomycin (Autoclave, pg. 5)
NERL™ Blood Bank Saline
Nerve Growth Factor
Neuraminidase, Type X and Type VIII
Nutrient Mixtures (HAM) F-10
Nutrient Mixtures (HAM) F-12
NZY Broth

O

Opti-MEM/Reduced Serum Medium

P

Pectin
Pectinase
•Penicillin (pg. 5)
Penicillinase Type 1
*pH 4 Calibration Buffer **(**without Phenylmercuric Acetate)
*pH 7 Calibration Buffer **(**without Phenylmercuric Acetate)
*pH 10 Calibration Buffer **(**without Phenylmercuric Acetate)
Phosphatase Alkaline, Type VII-NT,Bovine (without Glycerol)
*Phosphate Buffer Saline (PBS) (Unused only)
Phosphodiesterase
Phosphodiesterase 3', 5' Cyclic Nucleotide (Without Glycerol)
Plasmin
Polyoxyethylenesorbitan Monolaurate (Tween-20) (<5%)
Potassium Acetate
Potassium Bicarbonate
Potassium Bitartrate
*Potassium Chloride (≤1%)(stock solution must be submitted as chemical waste)
Potassium Phosphate (dibasic)
Potassium Phosphate (mono)
Potassium Thiosulfate
Proline & Isomer DL
•Puromycin (Autoclave, pg. 5)

Pyridoxal Phosphate

Q

R

Raffinose Pentahydrate
Riboflavin
Ribonuclease A
Ribonuclease S
Ribonuclease T1
Roswell Park Memorial Institute (RPMI) 1640 Medium
RPMI 1640 Medium Auto-Mod™ for Autoclaving
RPMI 1640 Medium Dutch Modification

S

Sarcosine
Schneider's Insect Media
Shields and Sang M3 Insect Medium
SmBM Smooth Muscle Cell Growth Basal Medium
Sodium Acetate
Sodium Ascorbate
Sodium Bicarbonate (Sodium Hydrogen Carbonate also known as Baking Soda)
Sodium Carbonate
Sodium Chloride (NaCl) (≤1%)
*Sodium Chloride Sodium Citrate (SSC) (1x)
Sodium Citrate
*Sodium Dodecyl Sulfate (Sodium Luaryl Sulfate) (SDS) (≤10% concentration)
Sodium Hydrogen Phosphate
*Sodium Hypochlorite Solution (Bleach) (≤10%)
Sodium Phosphate Buffer
Sodium Phosphate Dibasic
Sodium Phosphate Monobasic
Sodium Pyruvate
Sodium Sulfate
Sodium Thiosulfate
Starch
StemFlex Medium
Streptokinase
•Streptomycin (Autoclave, pg. 5)
Succinamide
Sucrose (and Isomers)
•Sulfadoxine (Autoclave, pg. 5)

Super Optimal Broth with Catabolite Repression (SOC) Medium

T

TAPS (3-{[tris(hydroxymethyl)methyl]amino}propanesulfonic acid)
TC-100 Insect Medium
Terrific Broth
• Tetracycline (Autoclave, pg. 5)
TMB Substrate Solution A
TNM-FH Insect Medium
Transferrin, Human
*Tricaine Methanesulfonate (MS-222) Buffered Solution (≤300mg/L)
Tricine [N-tris(hydroxymethyl)methylglycine]
TrypLE Select Enzyme
Tris
*Tris, Acetic Acid and EDTA (TAE) Buffer (1x)
*Tris Buffered Saline (TBS) (1x)
*Tris-EDTA (20mM Tris, 1mM EDTA)
*Tris-Glycine Buffer (1x)
Tris Hydrochloride (Tris-HCl)
*Triton X-100 Lysis Buffer (1x)
*Triton X-100 (≤1%)
*Trypsin Inhibitor (Undiluted stock must be submitted as chemical waste)
*Trypsin-EDTA (≤0.25%)
Tryptic Soy Broth Medium
Tryptone Peptone
*Tween-20 (Polyoxyethylenesorbitan Monolaurate) (≤5%)
*Tyrode's buffer (10mm HEPES, 137mM NaCl, 4.5mM Potassium Chloride, 0.5mM Magnesium Sulfate, 0.5mM Potassium Phosphate, 10mM Glucose, 1.8mM Calcium Chloride)

U

Urea

V

Vinegar (pH≤6)

W

Waymouth Medium MB
Whittens's Medium
William's Medium E

X

Y

Yeast Extract
Yeast Extract with Supplements (YES) Medium
Yeast extract, Peptone and Dextrose (YPD) Medium
YP-GAL Broth
*YT Culture Medium (2x)

Z

368. Abid Kazi

I am responding: On behalf of myself

Name: Abid Kazi

Name of Organization: Veteran Affairs - VAMC - Lebanon

Type of Organization: Government Agency

Role: Other

Role - Other: Health System Specialist

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Veteran Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Support for modernization and broader scope.
NIH's proposal to extend oversight beyond recombinant and synthetic nucleic acid research to include wild-type human pathogens, genetically modified organisms, toxins, and prions is appropriate and responsive to current scientific practice, and it aligns with stated goals to modernize biosafety and strengthen transparency and accountability.

Recommendation—clarify key terms to prevent inconsistent application.
Several terms central to scoping—particularly "biohazard," "biological agent," "genetic modification," and "genetically modified organism"—should be defined with greater precision in the policy text and/or companion guidance. Stakeholder comments indicate that definitional ambiguity could lead to inconsistent institutional interpretations, uneven review determinations, and confusion regarding coverage boundaries.
Address possible oversight gaps.

NIH should explicitly indicate whether research involving (a) non-pathogenic organisms engineered to express hazardous proteins, (b) prion-like, self-aggregating proteins not traditionally captured in RG frameworks, and (c) novel delivery platforms (e.g., gene drives) are fully encompassed under the draft scope, with cross-references to implementation resources or existing NIH considerations (e.g., gene drive materials) to avoid inadvertent gaps.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): General endorsement of tiering.
A tiered, risk-calibrated approach is appropriate and should reduce burden for well-characterized, lower-risk activities while directing federal attention to higher-risk or novel circumstances.

Recommendation—make thresholds and delegation criteria explicit.

The policy would benefit from clearly articulated criteria for when NIH review is required versus when IBCs may rely on published NIH precedents and local risk assessments. Stakeholder feedback encourages limiting NIH pre-approval to defined high-risk scenarios and allowing IBCs to manage routine low-risk work—improving timeliness without compromising safety.

Implementation consideration—resourcing for IBCs.
Because tiering transfers meaningful decision authority to IBCs, NIH should pair the model with implementation funding, training, and an escalation framework, ensuring that IBCs can consistently apply tiered oversight across institutions of varying capacity

3. Continued utility of Risk Groups: Balanced use of RGs and BSLs.
RGs provide a baseline hazard characterization anchored in pathogenicity and host range; BSLs translate risk into facility and practice requirements. For genetically modified agents, RGs alone may under- or over-estimate actual risk depending on phenotype; combining RG assignment with phenotype-informed adjustments and BMBL-aligned containment is preferable.

Recommendation—codify decision aids for modified agents.
NIH should include or reference practical decision aids that guide institutions in reconciling RG baselines with modified agent characteristics (e.g., altered tropism, attenuated virulence, novel delivery vectors) and in documenting the rationale for deviations from default RG-to-BSL mappings. A cross-walk or table of considerations, integrated with the draft's implementation resources, would enhance consistency.

Alignment with existing guidance.
Where NIH already provides focused biosafety considerations (e.g., gene drive modified organisms and other specialized areas), link these materials so committees can calibrate containment based on function and phenotype rather than nominal RG status alone.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Non-regulatory incentives.
To extend best practices beyond NIH-funded research, NIH could offer:

Access to training and templates (incident reporting, IBC minutes) and recognition programs for voluntary adopters (e.g., a registry or badge indicating alignment with NIH biosafety practices).
Model policies and implementation toolkits that smaller institutions can adapt, including staffing benchmarks, sample SOPs, and scalable digital reporting forms.

Collaborative networks and pilot programs.
NIH might seed regional biosafety collaboratives or pilot grants enabling non-funded institutions to adopt and evaluate the framework, building capacity through shared training and peer review. This approach responds to stakeholder concerns about resource gaps and could prevent uneven adoption.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Support for standardization.
Uniform templates can improve data quality and comparability across institutions, facilitating trend analysis and targeted prevention.

Recommendations to refine templates.

Proportional reporting thresholds: Clearly distinguish record-keeping vs. reportable incidents; provide examples to avoid over-reporting of near-misses that do not meaningfully inform safety improvements.
Privacy and IP protections: Include fields and instructions for redaction of confidential or proprietary information prior to public posting, balancing transparency with researcher privacy and institutional interests.
Machine-readable structure: Offer a data dictionary and machine-readable formats (e.g., CSV or JSON schemas) to streamline submission and enable analytics, especially if NIH proceeds with centralized incident aggregation and analysis.
Feedback loop: Provide guidance on corrective action documentation and standardized taxonomies for incident causes (e.g., human factors, equipment failure), improving cross-institution learning

6. Other feedback relevant to this resource: Implementation resources needed.

Phased timeline and readiness checklist: Publish phased milestones, staffing competencies, and minimum infrastructure requirements so institutions can plan budgets and hiring. Stakeholders have emphasized that new obligations—assurances, public postings, and expanded IBC roles—require proportionate support to avoid burden without safety gains.
IBC operations toolkit: Detailed guidance on IBC constitution, independence, escalation pathways, and integration with IRBs/IACUCs will promote consistency across the “three pillars” of oversight.
Costing guidance and funding mechanisms: Provide illustrative cost models (small, mid-size, large institutions), recommended FTEs, training budgets, and IT systems needs (for reporting, registries, public posting), alongside potential supplements or set-aside funds to offset implementation costs.
Special topics modules: Short, scenario-based resources (e.g., gene drive organisms, toxin work, prion-like proteins, lentiviral vectors) with containment rationales and example reviews to harmonize decisions nationwide.

Additional Note on Implementation Costs
Institutions—especially those with limited biosafety staffing—will incur non-trivial costs for policy adoption: new or expanded IBC operations, training, public-facing documentation systems, and incident analytics. To ensure the policy’s goals are met without disproportionate burden, NIH should (1) publish cost-impact assessments by institutional profile; (2) offer targeted funding or administrative supplements; and (3) stage implementation using pilot cohorts to validate resource assumptions and refine guidance. These steps reflect widely shared stakeholder concerns about pairing expanded responsibilities with practical authority, training, and support.

Uploaded File: NIH_Biosafety_Comments.docx

Description: Written response to the DRAFT policy.

Draft Formal Comments on NOT-OD-26-112: Draft NIH Biosafety Policy for Research Involving Biohazards

To Whom It May Concern:

Thank you for the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112). I appreciate NIH's efforts to modernize biosafety oversight and to develop a risk-based, transparent, and adaptive framework that reflects the evolving landscape of biomedical research. My comments below highlight areas of support as well as concerns regarding implementation feasibility, resource demands, and the potential impact on institutions of varying sizes and capacities.

1. Scope and Definitions

The expanded oversight of biohazards—including wild-type human pathogens, genetically modified organisms, toxins, and prions—represents an important modernization of biosafety governance. However, several key terms (e.g., 'biohazard,' 'genetic modification,' 'genetically modified organism') require clearer definitions to prevent inconsistent institutional interpretations and ensure accurate scoping of review responsibilities.

2. Risk-Based Oversight and Delegation Authorities

The introduction of risk-based review tiers and opportunities for delegated IBC review of lower-risk activities is a positive step toward streamlining oversight. Nonetheless, institutions would benefit from clearer thresholds for when NIH review is required versus when IBCs may rely on published precedents.

3. Administrative Burden and Implementation Costs

While the proposed framework aims to reduce administrative burden for low-risk research, the overall expansion of institutional obligations—including documentation, incident reporting, public posting requirements, assurances, and strengthened IBC functions—could impose significant new costs for institutions. This is of particular concern for smaller or resource-constrained organizations, which may lack dedicated biosafety infrastructure. Stakeholders have cautioned that without proportionate authority, resources, and training support, these expanded expectations may increase administrative workload without a corresponding improvement in risk mitigation.

I specifically urge NIH to:

• Provide clear cost-impact assessments for institutions of different sizes.

• Offer dedicated implementation funding or supplemental budget mechanisms for staffing, training, digital systems, and compliance activities.

• Consider a phased implementation schedule to allow institutions time to develop appropriate capabilities.

4. Reporting, Documentation, and Transparency Requirements

Standardized templates for incident reporting and IBC meeting minutes should improve consistency across institutions. However, stakeholders have noted the importance of balancing transparency with protection of confidential, sensitive, or proprietary information. Clear NIH guidance on redaction, privacy protections, and public-posting expectations would help institutions comply while safeguarding researcher privacy and intellectual property.

5. Expanded IBC Responsibilities and Required Institutional Support

The draft appropriately strengthens the role of the IBC as a core oversight body parallel to IRBs and IACUCs. Nevertheless, expanded responsibilities must be matched with commensurate authority, independence, and resource support. Biosafety professionals and IBCs need institutional backing—including staffing, training opportunities, and escalation pathways—to meet the expectations outlined in the policy.

6. Need for Additional Public Review and Implementation Resources

Given the scope of change proposed, further public review of implementation materials—including guidance documents, training resources, and reference tables—would help ensure successful adoption. Stakeholder groups have recommended an opportunity for comment on the next draft before finalization, noting current uncertainties related to institutional burden and operational feasibility.

Conclusion

NIH's modernization initiative is a vital step forward for biosafety oversight in the biomedical research enterprise. With further clarification of definitions, alignment of oversight thresholds, and the provision of adequate financial and operational support for implementation, the policy will be better positioned to achieve its goals of strengthening biosafety, enhancing accountability, and supporting safe research progress.

Thank you for considering these comments. I appreciate NIH's continued engagement with the research and biosafety community and look forward to future opportunities to contribute to the policy development process.

369. Angelo State University Institutional Biosafety Committee (IBC)

I am responding: On behalf of an organization

Name: Sam Spooner

Name of Organization: Angelo State University Institutional Biosafety Committee (IBC)

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Currently biosafety level one and level two research (BSLs 1-2)

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see the attachment.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see the attachment.

3. Continued utility of Risk Groups: Please see the attachment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see the attachment.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see the attachment.

6. Other feedback relevant to this resource: Please see the attachment.

Uploaded File: Draft-Biosafety-Policy-for-Research-Involving-Biohazards-Comments-19-Oct-26.pdf

Description: Comments submitted by Angelo State University Institutional Biosafety Committee

Draft Biosafety Policy for Research Involving Biohazards
Replaces the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

Comments Submitted by Angelo State University
Institutional Biosafety Committee (IBC)

The Angelo State University Institutional Biosafety Committee supports NIH's efforts to modernize and strengthen biosafety oversight and recognizes that many elements of the proposed policy are consistent with current institutional biosafety practices. We appreciate NIH's commitment to establishing a comprehensive, risk-based framework for research involving biohazards.

At the same time, the proposed expansion of scope, Biosafety Assurance requirements, incident-reporting obligations, and public disclosure provisions will create additional administrative and compliance responsibilities for institutions. We encourage NIH to provide clear implementation guidance, standardized templates, and adequate transition periods to support consistent adoption across institutions of varying size and capacity.

The Committee is particularly concerned about the proposed public posting of Institutional Biosafety Committee meeting minutes and incident reports. While transparency is an important objective, NIH should ensure appropriate safeguards protect confidential, proprietary, and security-sensitive information and give institutions flexibility in meeting public disclosure requirements.

Finally, we encourage NIH to consider the resource implications associated with these expanded requirements, particularly for smaller institutions with limited biosafety staffing and budgets. Maintaining a risk-based approach that preserves rigorous oversight of higher-risk research while allowing streamlined review of genuinely low-risk activities will support both effective biosafety governance and efficient use of institutional resources.

We appreciate the opportunity to provide comments and respectfully submit these recommendations for consideration.

370. Peter A Nigrovic

I am responding: On behalf of myself

Name: Peter A Nigrovic

Name of Organization: Boston Children's Hospital

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am concerned with the inclusion of "The introduction into cells, organisms, or viruses of nucleic acid molecules that...Can be transcribed or translated", which encompasses transient mRNA approaches, not suitable for regulation under this rule because it does not pose risks comparable to DNA modification. The rule must be revised to eliminate this term before finalization.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

371. AstraZeneca

I am responding: On behalf of an organization

Name:

Name of Organization: AstraZeneca

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attached

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see attached

3. Continued utility of Risk Groups: Please see attached

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see attached

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attached

6. Other feedback relevant to this resource: Please see attached

Uploaded File: Comments-to-Draft-NIH-Biosafety-Policy_19-October-2026.pdf

AstraZeneca PLC
19 October 2026

National Institutes of Health
Office of Science Policy

Re: Request for Comment on Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear NIH Office of Science Policy:

AstraZeneca appreciates the opportunity to provide comments on the National Institutes of Health (NIH) Draft Biosafety Policy for Research Involving Biohazards. We support NIH's efforts to modernize biosafety oversight and establish a framework that reflects the evolving nature of biomedical research. The proposed policy represents a significant expansion of the current NIH Guidelines by extending oversight beyond recombinant and synthetic nucleic acid research to a broader range of biohazards. As a research-based biopharmaceutical company that may be subject to the policy through direct or indirect federal funding mechanisms, AstraZeneca has a strong interest in ensuring the final policy is clear, risk-based, operationally feasible, and adaptable to both academic and commercial research environments.

We respectfully offer the following observations and recommendations for NIH's consideration.

Transparency Requirements and Protection of Proprietary Information

AstraZeneca supports the policy's emphasis on transparency and public accountability in biosafety oversight. At the same time, we are concerned about the proposal requiring institutions to publicly post Institutional Biosafety Committee (IBC) meeting minutes and incident reports, as well as maintain publicly available IBC rosters.

While transparency is an important objective, commercial research organizations face unique challenges related to the protection of proprietary information, confidential business information, and intellectual property. In some circumstances, the absence of clear redaction standards may create uncertainty regarding the protection of proprietary information, confidential business information, and intellectual property, particularly when discussions involve novel technologies, development strategies, platform approaches, manufacturing activities, or other proprietary research.

AstraZeneca appreciates that the draft policy provides for “appropriate and allowable redactions” before IBC meeting minutes and incident reports are publicly posted and recognizes protection of proprietary interests as a relevant consideration in determining whether IBC meetings should be open to the public. However, AstraZeneca encourages NIH to provide explicit protections for

proprietary information, confidential business information and intellectual property, including clear guidance regarding the scope of "appropriate and allowable redactions" before IBC meeting minutes and incident reports are publicly posted. Such guidance should recognize the need to protect unpublished inventions, patent-sensitive technical information, trade secrets, confidential know-how, proprietary biological materials and constructs, unpublished research plans and results, and information subject to third-party confidentiality obligations.

NIH should also clarify that appropriately redacted records will satisfy the public-posting requirement, provided the public version adequately describes the biosafety assessment, safeguards imposed, and IBC disposition.

We also encourage NIH to evaluate whether public posting of individual IBC membership information is necessary in all circumstances and to consider employee privacy, security, and proprietary considerations for commercial organizations.

Authorized Organizational Representative (AOR) Responsibilities

The draft policy introduces a Biosafety Assurance mechanism submitted through an Authorized Organizational Representative (AOR), replacing certain existing registration and reporting requirements.

AstraZeneca supports efforts to streamline administration and reduce unnecessary burden; however, additional clarity regarding the role and responsibilities of the AOR would improve implementation. The final policy would benefit from a more detailed description of the authority, accountability, and expectations associated with the AOR function, including how this role interacts with the IBC Chair, Biological Safety Officer, institutional leadership, and broader compliance framework. Additional clarity regarding documentation requirements and oversight expectations during the four-year assurance period would also be helpful.

Applicability to Non-NIH-Funded Research

AstraZeneca requests additional clarification regarding the policy's applicability to non-NIH-funded research conducted at institutions that receive NIH funding.

Given the breadth of this provision, additional guidance would be helpful regarding how these requirements apply across large organizations, affiliates, subsidiaries, collaborative research arrangements, and independently funded research activities. Clarification in this area would help institutions understand the intended scope of compliance obligations and facilitate consistent implementation.

Institutional Biosafety Committee Governance

While the draft policy establishes requirements for IBC membership and responsibilities, AstraZeneca believes additional foundational guidance regarding IBC governance would be beneficial.

The final policy should further clarify the qualifications and responsibilities associated with positions such as the IBC Chair, Biological Safety Officer, community representatives, and institutional representatives. Additional guidance on training expectations and minimum competency standards would help promote consistency across institutions and ensure appropriate expertise is available for increasingly complex research activities.

Considerations for Commercial Research Organizations

AstraZeneca notes that the policy does not provide specific implementation considerations for commercial research organizations. Commercial research organizations may maintain biosafety governance structures that differ from traditional academic models.

Additional implementation guidance describing how such organizations can demonstrate compliance with the policy would be valuable and would help ensure consistent interpretation of requirements across different institutional settings.

Continued Role of Risk Groups

AstraZeneca believes Risk Groups remain an important and widely understood framework for hazard characterization, risk communication, and risk assessment.

We recommend maintaining Risk Group definitions and concepts within the final policy itself while continuing to support their use in conjunction with biosafety levels and project-specific risk assessments. Retaining these concepts in the policy would support consistency across institutions, facilitate implementation, and provide an important foundation for risk-based decision making.

Incident Reporting Thresholds and Definitions

AstraZeneca supports robust incident reporting systems and recognizes the value of collecting information that can improve biosafety practices across the research enterprise. However, greater clarity regarding incident-reporting thresholds would improve consistency and implementation.

Additional guidance would be helpful regarding the distinction between major and minor incidents, including consideration of factors such as the nature of the biological agent, containment level, volume involved, potential exposure risk, and potential environmental impact. Further clarification regarding what constitutes a "significant risk to human health," as well as illustrative examples of

reportable and non-reportable events, would promote more consistent decision making across institutions.

AstraZeneca also encourages NIH to describe how collected incident information will be analyzed and used to advance biosafety practices and whether aggregate lessons learned will be shared with the research community.

Clinical Research Considerations

The draft policy provides limited discussion regarding application of the framework to clinical research involving investigational products.

Additional guidance regarding how biosafety assessments should be conducted in clinical research settings would promote more consistent implementation across institutions. NIH should consider providing examples or supplemental guidance regarding the application of the policy to emerging therapeutic modalities and clarify when risk assessments may be sufficient to address biosafety considerations in clinical research settings.

Given the increasing use of complex modalities, including gene therapies, genetically modified cell therapies, and other advanced biologics, additional clarity would support consistent oversight while maintaining appropriate protections for research participants, personnel, and the public.

Delegated and Subcommittee Review Processes

The policy would benefit from additional detail regarding circumstances under which delegated, administrative, or subcommittee review may be used.

Further clarification regarding appropriate use of delegated review mechanisms would support efficient implementation while allowing committees to focus resources on higher-risk activities. Clear criteria distinguishing activities requiring full committee review from those suitable for delegated review would reduce administrative burden without compromising safety.

Guidance for Large-Scale Research Activities

AstraZeneca encourages NIH to ensure that sufficient guidance remains available regarding large-scale research activities and scale-up operations if information currently contained within the NIH Guidelines is relocated to supporting implementation materials.

Clear expectations for these activities will remain important for institutions conducting research beyond small laboratory scale and will help ensure consistent biosafety practices across a range of research and development environments.

Definitions and Terminology

Finally, AstraZeneca recommends that NIH ensure all acronyms and specialized terminology are clearly defined and used consistently throughout the policy and associated implementation materials.

A comprehensive glossary would improve usability, support consistent interpretation, and reduce ambiguity during implementation. Consistent terminology will be particularly important as the policy expands in scope and applicability across a broader range of research institutions and activities.

Conclusion

AstraZeneca appreciates NIH's commitment to modernizing biosafety oversight and welcomes continued engagement as the policy is finalized. We believe the recommendations outlined above would improve clarity, support consistent implementation across a diverse research ecosystem, and help achieve NIH's goals of enhancing biosafety, transparency, and accountability while preserving protection of confidential commercial information and enabling continued scientific innovation.

Thank you for the opportunity to provide comments on this important policy proposal.

Sincerely,

AstraZeneca PLC

372. Sahin Naqvi

I am responding: On behalf of myself

Name: Sahin Naqvi

Name of Organization: Boston Children's Hospital

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Molecular biology, developmental biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am commenting specifically on NOT-OD-26-112, and specifically on the section "Genetic modification" within "General Definitions." This section states:

The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
- Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
- Have the potential for one or more cycles of replication in a cell; or
- Can be transcribed or translated;

Transient expression of nucleic acids that “can be transcribed or translated” is not a genetic modification by definition. For example, transient expression plasmids, even if provided as DNA, do not replicate within eukaryotic cells and cannot stably integrate into the genome. Similarly, mRNA delivered by transfection or nanoparticles cannot replicate and is only translated into protein products. Besides the incorrect biological assignment of such nucleic acids to genetic modifications, the proposal would also have unwanted practical implications: it would require the reporting of any transient expression system (which is incredibly widespread among the biomedical research community) as a Biohazard, adding a large amount of regulatory oversight and burden to scientists. This would achieve the opposite of what the proposal intends.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

373. Dr. Sandra Poulson

I am responding: On behalf of myself

Name: Dr. Sandra Poulson

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Pain Neurobiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of the new policy is too broad and does not take into consideration the low level of risk of use of Adeno-associated Viruses, one of the most ubiquitous and heavily used modern neuroscience tools. This tool has revolutionized how we study neurons and what neurons do and how they affect behavior, and yet this policy makes no mention or consideration for how this tool will be affected. If the scope does not take into account increasesed difficulty of using this tool, this policy is at risk of threatening the access and usage of this tool for all new neuroscience labs going forward. Careful consideration for not restricting the use of AAVs should be incoporated into the policy so that neuroscience research is not impeded.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Does not clearly define tiers of oversight; our Adeno-associated viruses are BSL-1 and pose little risk to users and to research models, but the draft leaves ambiguity in how these would be treated

3. Continued utility of Risk Groups: Explicit categorization of Adeno-associated viruses for use for neuroscience research needs to be addressed. Do not hinder neuroscience research with strict unnecessary oversight.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: There needs to be explicit incorporation for how Adeno-associated viruses, lenti viruses, modified replication deficient rabies viruses and associated helper viruses, and other modern neuroscience viral tools are handled. This policy seems to target gain-of-function viral research in light of the COVID-19 pandemic which is a laudable effort. But this policy does not take into account the viral tools that US neuroscientists use to study neural function and the effect on behavior. Explicit treatment of these viral tools needs to be outlines such that use in US laboratories is

not hindered to the point of restricting neuroscience research. More attention and care needs to be put into this policy to protect these modern tools.

374. American Association of Immunologists

I am responding: On behalf of an organization

Name: Emily Kansler, PhD

Name of Organization: American Association of Immunologists

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Manager, Science Policy

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The American Association of Immunologists (AAI) appreciates NIH's efforts to modernize and strengthen biosafety practices when conducting biomedical research. AAI supports NIH's goals of augmenting public safety, transparency, and accountability when it comes to biosafety, but believes that this policy, as written, would not make meaningful progress toward these goals. It would, however, significantly increase the burden on researchers and institutions and slow scientific progress. AAI elaborates on these concerns in each of the categories below.

The draft policy significantly expands the scope of research covered by NIH's current biosafety framework beyond research involving recombinant and synthetic nucleic acids to include all wild-type pathogens that cause disease in humans; all genetically modified cells, viruses, and organisms (other than plants) toxins, prions, and other self-aggregating proteins; and, cells and organisms (other than plants) that contain any of the above. This proposal appears to bring many experiments and types of research that have historically been considered to have no or low risk and to be exempt from Institutional Biosafety Committee (IBC) review into the new oversight framework (see Appendix C. Exemptions Under Section III-F-8 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules). Much of this previously exempt and low-risk research will now require review and approval before initiation. While research listed under Section IV-3 of the current draft policy may be delegated to an individual or subgroup of IBC members, AAI is deeply concerned about the significant increase in administrative burden imposed on investigators, institutions, and IBCs. Further, AAI has significant hesitation about the feasibility of IBCs reviewing and approving such a vast expanse of research, especially when this additional review is unlikely to result in any meaningful improvement in biosafety. AAI urges NIH to carefully consider meaningful exemptions for research that is well characterized, routinely performed, and associated with little to no biosafety risk. Without such exemptions, as were previously allowed, AAI is concerned that IBCs will become overwhelmed with large volumes of low-risk protocols, potentially diverting attention from higher-risk activities that deserve more intensive scrutiny.

AAI is similarly alarmed about the substantial administrative burden imposed by the policy applying to all existing awards and ongoing research activities rather than only newly funded projects. Requiring institutions to retrospectively review large numbers of ongoing experiments will create substantial workload for investigators, IBCs, and institutions, potentially halting or delaying active research without a corresponding improvement in safety. AAI urges NIH to consider ways to reduce this burden and prioritize the review of higher-risk research.

The draft policy states that "as a term and condition for NIH funding, institutions shall ensure that any research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with this Policy." While AAI appreciates NIH's intent to standardize biosafety across the biomedical research enterprise, AAI is troubled that the policy would expand NIH oversight and authority to non-NIH funded projects. Any effort to harmonize how potentially risky research is conducted across federal agencies should be led by an entity that has broad oversight over federally funded scientific research, not by a single funding agency.

In addition, AAI believes that requiring "de novo registration submission and review" every three years, a new obligation not previously required under the old policy, is unnecessarily burdensome and disruptive for the investigator and IBC. Overall, many aspects of this policy place substantial workload and capacity requirements upon the IBC and individual investigators, without additional support. AAI is particularly concerned that smaller institutions with less resources may be excessively burdened by this policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): AAI supports the principle that biosafety oversight should be calibrated to risk, and that higher-risk research should receive greater examination than lower-risk research. The delegated review pathway under Section IV-3 is well-intentioned; however, AAI believes the draft policy should provide clearer oversight mechanisms for institutions to conduct streamlined or minimal reviews (if not exemptions) of research previously known to be low risk (e.g., research conducted with transgenic organisms at BSL-1/ABSL-1). Delegating review and approval to one or a subgroup of IBC members only increases the burden on one or more individuals who may or may not have the expertise to accurately determine biosafety risk. Research exempt under the previous policy should, at minimum, undergo an expedited or streamlined review process to reduce administrative burden that otherwise has no clear safety benefit. This approach would better align oversight requirements with actual risk and preserve IBC capacity for activities with true biosafety concerns.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: AAI appreciates that NIH places transparency at the forefront of its biosafety policy and supports efforts to standardize incident reporting in ways that facilitate the identification of systemic biosafety issues and promote continuous improvement. At the same time, AAI encourages NIH to carefully consider the unintended consequences of requiring public posting of all incident reports, in part because incidence reports must contain identifiable information such as principal investigator names and position titles of individuals

involved in an incident. Providing even this information, alongside publicly available lab websites that list personnel, enables easy identification of those involved. This raises privacy and security concerns for investigators, research staff, and institutions. In some research areas, including clinical studies and research involving animals, researchers and institutions may be subject to heightened public attention or scrutiny. To balance transparency with safety and privacy concerns, NIH should consider limiting the disclosure of and protecting personally identifiable information.

In addition, mandatory public posting of all incidents, including low-risk incidents, could have the unintended consequence of discouraging reporting if public disclosure carries reputational or personal concerns. If NIH's objective is to strengthen biosecurity practices and identify meaningful areas of improvement or risk across the biomedical research enterprise, AAI encourages NIH to consider mechanisms that better protect individual identities, including anonymous reporting.

6. Other feedback relevant to this resource: AAI appreciates NIH's commitment to providing additional guidance through supplemental materials and implementation resources. Given the significant expansion in scope of the draft policy, AAI urges NIH to provide specific guidance for the newly covered areas (wild-type pathogens, toxins, etc.) since institutions and IBCs may need to build oversight capacity from scratch. Similarly, guidance should include concrete risk-assessment examples across a range of research types. NIH may also consider developing a tool for investigators and IBCs to quickly determine which oversight tier is appropriate for assessment of a proposal. These resources should be made available well before the implementation date.

Finally, AAI worries that the proposed implementation deadline of six months from final policy publication is inadequate, especially for smaller institutions and/or those without an existing IBC or biosafety oversight infrastructure. In addition, given the expanded scope, current IBCs may lack members with relevant expertise and need sufficient time to establish an appropriate roster.

Uploaded File: AAI-response-to-Draft-NIH-Biosafety-Policy_Final_10192026.pdf

Submission by the American Association of Immunologists (AAI) in response to the National Institutes of Health (NIH) Request for Information (RFI): Draft NIH Biosafety Policy for Research Involving Biohazards

October 19, 2026

The American Association of Immunologists (AAI) appreciates NIH's efforts to modernize and strengthen biosafety practices when conducting biomedical research. AAI supports NIH's goals of augmenting public safety, transparency, and accountability when it comes to biosafety, but believes that this policy, as written, would not make meaningful progress toward these goals. It would, however, significantly increase the burden on researchers and institutions and slow scientific progress. AAI elaborates on these concerns in each of the categories below.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

The draft policy significantly expands the scope of research covered by NIH's current biosafety framework beyond research involving recombinant and synthetic nucleic acids to include all wild-type pathogens that cause disease in humans; all genetically modified cells, viruses, and organisms (other than plants) toxins, prions, and other self-aggregating proteins; and, cells and organisms (other than plants) that contain any of the above. This proposal appears to bring many experiments and types of research that have historically been considered to have no or low risk and to be exempt from Institutional Biosafety Committee (IBC) review into the new oversight framework (see Appendix C. Exemptions Under Section III-F-8 of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules). Much of this previously exempt and low-risk research will now require review and approval before initiation. While research listed under Section IV-3 of the current draft policy may be delegated to an individual or subgroup of IBC members, AAI is deeply concerned about the significant increase in administrative burden imposed on investigators, institutions, and IBCs. Further, AAI has significant hesitation about the feasibility of IBCs reviewing and approving such a vast expanse of research, especially when this additional review is unlikely to result in any meaningful improvement in biosafety. AAI urges NIH to carefully consider meaningful exemptions for research that is well characterized, routinely performed, and associated with little to no biosafety risk. Without such exemptions, as were previously allowed, AAI is concerned that IBCs will become overwhelmed with large volumes of low-risk protocols, potentially diverting attention from higher-risk activities that deserve more intensive scrutiny.

AAI is similarly alarmed about the substantial administrative burden imposed by the policy applying to all existing awards and ongoing research activities rather than only newly funded projects. Requiring

institutions to retrospectively review large numbers of ongoing experiments will create substantial workload for investigators, IBCs, and institutions, potentially halting or delaying active research without a corresponding improvement in safety. AAI urges NIH to consider ways to reduce this burden and prioritize the review of higher-risk research.

The draft policy states that "as a term and condition for NIH funding, institutions shall ensure that any research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with this Policy." While AAI appreciates NIH's intent to standardize biosafety across the biomedical research enterprise, AAI is troubled that the policy would expand NIH oversight and authority to non-NIH funded projects. Any effort to harmonize how potentially risky research is conducted across federal agencies should be led by an entity that has broad oversight over federally funded scientific research, not by a single funding agency.

In addition, AAI believes that requiring "*de novo* registration submission and review" every three years, a new obligation not previously required under the old policy, is unnecessarily burdensome and disruptive for the investigator and IBC. Overall, many aspects of this policy place substantial workload and capacity requirements upon the IBC and individual investigators, without additional support. AAI is particularly concerned that smaller institutions with less resources may be excessively burdened by this policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).

AAI supports the principle that biosafety oversight should be calibrated to risk, and that higher-risk research should receive greater examination than lower-risk research. The delegated review pathway under Section IV-3 is well-intentioned; however, AAI believes the draft policy should provide clearer oversight mechanisms for institutions to conduct streamlined or minimal reviews (if not exemptions) of research previously known to be low risk (e.g., research conducted with transgenic organisms at BSL-1/ABSL-1). Delegating review and approval to one or a subgroup of IBC members only increases the burden on one or more individuals who may or may not have the expertise to accurately determine biosafety risk. Research exempt under the previous policy should, at minimum, undergo an expedited or streamlined review process to reduce administrative burden that otherwise has no clear safety benefit. This approach would better align oversight requirements with actual risk and preserve IBC capacity for activities with true biosafety concerns.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.

AAI appreciates that NIH places transparency at the forefront of its biosafety policy and supports efforts to standardize incident reporting in ways that facilitate the identification of systemic biosafety issues and promote continuous improvement. At the same time, AAI encourages NIH to carefully consider the

unintended consequences of requiring public posting of all incident reports, in part because incidence reports must contain identifiable information such as principal investigator names and position titles of individuals involved in an incident. Providing even this information, alongside publicly available lab websites that list personnel, enables easy identification of those involved. This raises privacy and security concerns for investigators, research staff, and institutions. In some research areas, including clinical studies and research involving animals, researchers and institutions may be subject to heightened public attention or scrutiny. To balance transparency with safety and privacy concerns, NIH should consider limiting the disclosure of and protecting personally identifiable information.

In addition, mandatory public posting of all incidents, including low-risk incidents, could have the unintended consequence of discouraging reporting if public disclosure carries reputational or personal concerns. If NIH's objective is to strengthen biosecurity practices and identify meaningful areas of improvement or risk across the biomedical research enterprise, AAI encourages NIH to consider mechanisms that better protect individual identities, including anonymous reporting.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

AAI appreciates NIH's commitment to providing additional guidance through supplemental materials and implementation resources. Given the significant expansion in scope of the draft policy, AAI urges NIH to provide specific guidance for the newly covered areas (wild-type pathogens, toxins, etc.) since institutions and IBCs may need to build oversight capacity from scratch. Similarly, guidance should include concrete risk-assessment examples across a range of research types. NIH may also consider developing a tool for investigators and IBCs to quickly determine which oversight tier is appropriate for assessment of a proposal. These resources should be made available well before the implementation date.

Finally, AAI worries that the proposed implementation deadline of six months from final policy publication is inadequate, especially for smaller institutions and/or those without an existing IBC or biosafety oversight infrastructure. In addition, given the expanded scope, current IBCs may lack members with relevant expertise and need sufficient time to establish an appropriate roster.

375. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: My lab uses adeno-associated viral (AAV) vectors to investigate how genes and proteins in specific brain cell types contribute to pain and addiction. These are engineered tools that are used routinely by labs across the country. Specifically, they cannot replicate, do not cause disease, and are classified at the lowest biosafety level (BSL-1) by our institution. Every AAV that we use has already been reviewed and approved by our Institutional Biosafety Committee (IBC). The draft policy would disrupt this rigorous approval process without providing any guidance on next steps or implementation of the policy.

Researchers, like myself, are left with an unclear picture of what will happen to already approved research. Can we keep working under our current approvals or do we need to pause active, funded projects? Do we have to resubmit everything from scratch once the policy is in place? Can we amend existing protocols? Without clear answers, institutions will take the safest legal route: stop everything and resubmit. This could set our research back by months or more for tools that have already undergone risk assessment and have been in use for years. The impact on innovation and expedient dissemination of results would be immediate.

The draft also lumps all viral vector research into a single broad category without the practical guidance that the current NIH Guidelines provide. The existing guidelines include specific, usable direction for common research tools like AAVs — what containment is required, how to assess risk, what paperwork is needed. The new policy removes all of that without replacing it. Investigators and biosafety committees will be left guessing, and different institutions will interpret the rules differently, creating a patchwork of inconsistent oversight across the country. Overall, the policy creates a broad new biosafety framework without providing enough specific, operational guidance for one of the most common experimental platforms in basic neuroscience.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The three-year renewal requirement is the most troublesome piece of this draft for our group's research. We have hundreds of approved AAV constructs. Every three years, we would need to resubmit them all; vectors that have not changed, that have been used safely year after year, that our IBC has already reviewed and

approved. There is no safety justification for this. NIH should allow institutions to use a "master protocol" approach, where a single protocol covers an entire class of well-characterized vectors, with individual new constructs added through a simple review process. Resubmitting hundreds of unchanged protocols every three years is not a safety measure.

What the draft also does not acknowledge is the real cost of all this compliance work. Tracking renewal deadlines for hundreds of constructs, preparing detailed incident reports within 24 hours, managing the public posting of meeting minutes, meeting new committee composition requirements; none of this happens for free. Most research labs do not have dedicated administrative staff for biosafety compliance. The practical result is that someone in the lab, a postdoc, a lab manager, the PI, will have to do it, taking time away from research. Or the lab will need to hire additional staff, which means spending grant money on administration instead of science. NIH has not estimated what this policy will cost the research community, and it should before moving forward.

The concept of tiered oversight, or matching the level of review to the actual level of risk, is the right approach in principle. However, the draft doe not define the tiers clearly enough to use them. Our AAVs are BSL-1 materials: the lowest risk category that exists. They cannot replicate, they do not cause disease in healthy people, and they have been used safely in research laboratories for decades. Yet under this draft, it is not clear that they would qualify for a lighter-touch review track. Without explicit criteria, our institution will default to full IBC review for everything, adding months of overhead for materials that pose no meaningful hazard. The impact will be felt most by those who can least afford it. Junior faculty who are just starting their labs are building their research programs from scratch, generating new AAV constructs, and submitting initial protocols. Graduate students and postdoctoral researchers are also directly harmed. NIH has invested heavily in fellowship and training programs specifically designed to help trainees complete their work on time. Administrative delays caused by this policy work directly against those investments.

3. Continued utility of Risk Groups: Our AAVs start from a naturally occurring virus, but that virus has been extensively modified. Specifically, key genes that allow it to replicate have been removed entirely. What remains cannot reproduce, cannot spread, and cannot cause disease. Our institution classifies these vectors as BSL-1 specifically because of those modifications. But if risk classification starts from the parental virus's RG category, none of that transformation is captured. We would be assessed against the natural virus, not the tool we actually use.

Biosafety Levels (BSLs) are a better fit for this kind of work because they describe what safety practices are actually required in the lab. Our AAVs are classified BSL-1, meaning they require standard lab practices and no special containment. That classification reflects the actual risk of working with these materials. I strongly recommend that BSL serve as the primary framework for classifying genetically modified research tools, with RG used only as a starting point when the research involves or is closely related to the natural, unmodified version of an agent. If RG is kept as the primary system, the policy must spell out exactly how classifications are adjusted for genetic modification. As it stands, different institutions are making those adjustments differently, leading to inconsistent and sometimes arbitrary differences in what is allowed and under what conditions.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The draft does not give non-NIH institutions a realistic path to implement the biosafety practices expected of NIH-funded institutions. The main obstacle for most of these institutions is not willingness, but capacity. Many may not have a full-time biosafety officer, an established safety committee, or staff with experience reviewing viral vector research. Asking them to voluntarily adopt a complex new framework without providing model templates, training resources, or step-by-step guidance is not a strategy that will work. Voluntary compliance provisions need to be paired with real tools that make compliance achievable for smaller or less-resourced institutions.

The draft also misses an important opportunity to reduce unnecessary duplication. Some non-NIH institutions are already operating under rigorous federal safety oversight via the CDC, USDA, FDA, or DOD. They are not operating without safeguards; they are operating under different but comparably strict ones. Rather than requiring these institutions to build a parallel compliance structure just to meet NIH's framework, the policy should formally recognize equivalent oversight programs.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting template requires a report within 24 hours for any "serious" incident, but the template never defines what "serious" means for research using BSL-1 viral vectors. A needlestick during an AAV injection is not the same as an exposure to a dangerous pathogen, but the draft treats them as if the same reporting process applies. Without a clear, practical definition that accounts for what the actual material is and what real risk it poses, labs and biosafety offices will not know how to apply this requirement consistently. Some will report everything out of caution; others will under-report. Neither is the right outcome. The template needs to include plain-language guidance that helps labs determine whether a given event actually requires a 24-hour report.

The public posting requirement for IBC meeting minutes raises a serious problem that the template does not address at all. IBC minutes describe ongoing research often in detail and often before that research has been published or patented. Posting five years of unredacted minutes publicly would expose unpublished findings, novel research tools, and investigator-specific information. This is not a hypothetical concern; it is a predictable consequence of the requirement as written. The template must specify what can and cannot be redacted before posting, and institutions need clear legal authority to make those redactions. Without that, the requirement will either discourage candid discussion in IBC meetings or result in researchers' unpublished work becoming public. The template also needs to allow batch review entries for labs with many similar constructs. Requiring a separate detailed entry for each of hundreds of nearly identical AAV vectors would make meeting minutes unmanageably long.

6. Other feedback relevant to this resource: This draft cannot be put into practice as written. Too many of the questions that labs and biosafety committees need answered are left for "future guidance". However, the six-month implementation clock starts when the policy is finalized, not when the guidance is ready. That means institutions will be expected to comply with a policy they cannot yet fully interpret. The result will be inconsistency, confusion, and for many labs research pause while they wait for clarity.

An effective date should not be set until the supporting guidance is finalized and publicly available. Six months is not enough time to restructure compliance systems when the practical meaning of the policy is still being worked out. Clear written direction for labs with existing IBC approvals needs to be provided.

Are current approvals still valid? Do we have to resubmit? Can we amend existing protocols? Without explicit answers to these basic questions, institutions will require full resubmission of everything to be safe. Transparency and honesty about what this policy will cost is necessary. Keeping up with renewal deadlines, writing 24-hour incident reports, managing public minute posting, and meeting new committee requirements all take real time and real money. Most labs do not have the staff to absorb this. Investigators will either redirect their own time from research to paperwork, or spend grant funding on additional administrative personnel. NIH has not estimated this cost or weighed it against the safety benefits. It should.

The impact on junior faculty and trainees should be acknowledged and addressed. A new faculty member building their lab from scratch, generating their first AAV constructs, and establishing their IBC protocols is in a fundamentally different position than an established lab. They have less staff, less institutional support, and less margin for administrative delays. NIH also funds thousands of graduate students and postdocs through fellowships and training grants built on the assumption that trainees can complete their work on schedule. Paperwork-driven delays undermine that assumption directly. NIH should be required to assess the impact of this policy on trainee timelines and early-career productivity before it is finalized.

376. People for the Ethical Treatment of Animals

I am responding: On behalf of an organization

Name:

Name of Organization: People for the Ethical Treatment of Animals

Type of Organization: Non-Profit Research Organization

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We support NIH's proposed expansion of biosafety oversight beyond recombinant and synthetic nucleic acid research to encompass a broader range of biological hazards. The expanded scope appropriately recognizes that biosafety risks are not limited to genetically modified agents and can arise from wild-type pathogens and other biological materials. The draft policy specifically notes that oversight would include wild-type agents and other biohazards, which is an important modernization of the current framework.

However, the draft creates a significant gap in oversight for zoonotic pathogens carried by animals used in experiments, particularly imported nonhuman primates. Imported nonhuman primates may harbor zoonotic pathogens unrelated to the approved research project, including pathogens that are not readily identified through routine screening. For example, the CDC has reported multiple cases of melioidosis caused by Burkholderia pseudomallei in imported macaques from Cambodia.1 B. pseudomallei is a Tier 1 Select Agent and can cause severe disease in humans. Tuberculosis has also been documented in imported macaques, including Mycobacterium orygis, which was identified in macaques from Southeast Asia and had not previously been documented in nonhuman primates imported into the United States.2 Cases of tuberculosis have also been identified after mandatory import quarantine, highlighting the limitations of routine screening and the potential for infections to go undetected.3 Antimicrobial-resistant bacteria are another concern, as they can cause serious infections that are difficult to treat. In 2023, vancomycin-resistant Staphylococcus aureus, a rare and highly drug-resistant bacterium, was identified in macaques imported from Mauritius and housed at the Oregon National Primate Research Center.4 Herpes B virus is also widespread among adult macaques, and infected animals can shed the virus without showing symptoms, posing a potentially fatal risk to humans. Routine screening for the virus is not required during import quarantine. CDC has also noted that imported nonhuman primates may develop disease months or years after importation, and that human exposure can occur through contact with infectious animal materials and bodily fluids.

The policy excludes many exposures to adventitious agents from federal reporting unless they result in a laboratory-acquired infection. While these agents may not be the focus of the experimental protocol,

they present substantial occupational and public health risks.

This oversight is at odds with the draft policy's broader recognition of zoonotic hazards. NIH defines a zoonotic agent as one reasonably suspected of transmission from animals to humans with the potential to cause human disease and establishes federal involvement in determining appropriate containment for certain emerging, novel, or zoonotic biological agents.

Whether a pathogen was deliberately introduced as part of an experiment or was carried by an animal does not determine the potential consequences of an exposure. The final policy should ensure that exposures to zoonotic pathogens associated with animals used in experiments are treated as biosafety events even when the pathogen is not part of the experimental protocol and no infection is ultimately confirmed. These exposures warrant federal attention and analysis.

1. Taetzsch SJ, Swaney EM, Gee JE, et al. Melioidosis in cynomolgus macaques (Macaca fascicularis) imported to the United States from Cambodia. Comp Med. 2022;72(6):394-402. doi:10.30802/AALAS-CM-22-000024
2. Swisher SD, Taetzsch SJ, Laughlin ME, et al. Outbreak of Mycobacterium orygis in a shipment of cynomolgus macaques imported from Southeast Asia–United States, February–May 2023. MMWR 2024;73(7):145-148. doi:10.15585/mmwr.mm 7307a2
3. Swisher SD, Taetzsch SJ, Laughlin ME, et al. Characteristics of tuberculosis tests performed during post import quarantine of nonhuman primates, United States, 2021 to 2024 [published online July 1, 2025]. J Am Assoc Lab Anim Sci. doi:10.30802/ AALAS-JAALAS-25-057
4. Bochart R, et al. Identification of vancomycin resistance in methicillin-resistant Staphylococcus aureus in two macaque species and decolonization and long-term prevention of recolonization in cynomolgus macaques (Macaca fascicularis). Front Immunol. 2023;14:1244637. doi:10.3389/fimmu.2023.1244637

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed delineation between local and federal oversight may understate risks associated with zoonotic exposures involving nonhuman primates.

The draft policy identifies events such as animal bites, scratches, escapes, improper disposition, and other incidents involving animals housed in BSL-1/ABSL-1 or BSL-2/ABSL-2 facilities to local IBC review, without required reporting to NIH. It also specifically exempts treatment following potential exposure to adventitious agents such as nonhuman primate Herpes B or B. pseudomallei from NIH reporting unless a laboratory-acquired infection occurs. These provisions risk hiding information that could reveal recurring hazards associated with the use of particular animals or animal sources, even those used by facilities in different local jurisdictions, which could create risks beyond a single institution.

Federal oversight should be required for:

*Any bites, scratches, and mucosal exposures involving imported nonhuman primates.
*Incidents requiring post-exposure prophylaxis or precautionary medical treatment following exposure to imported nonhuman primates.
*Detection of significant zoonotic pathogens in imported nonhuman primates used in NIH-funded research.

These incidents should not be treated solely as local occupational health matters because they provide important information about broader biosafety risks across the research enterprise. Federal reporting would enable NIH to determine whether patterns exist across institutions, species, animal sources, or types of experiments that cannot be identified through isolated institutional review.

NIH should also resist treating administrative burden as a reason to exclude genuine hazards from meaningful oversight. The draft policy is explicitly intended to calibrate oversight to risk. Where an activity presents a significant occupational or public health hazard, additional review, documentation, and reporting are appropriate consequences of that risk.

3. Continued utility of Risk Groups: No comment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): For institutions and other entities not subject to the policy, NIH should encourage adoption of the same core principles for research involving biohazards, including meaningful incident reporting, public transparency, and oversight of zoonotic hazards associated with animals used in experiments. An institution's biosafety accountability should not be stronger or weaker based on its funding sources.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: There must be meaningful public transparency regarding biosafety incidents. We urge NIH to retain its requirements for public posting of IBC meeting minutes and incident reports.

The public has a legitimate interest in knowing where federally supported research involving biological hazards is conducted, the nature of biosafety incidents associated with that research, and what actions institutions take in response. Aggregate reporting alone would make it substantially more difficult for the public to identify recurring problems associated with particular institutions, projects, or research practices. NIH should therefore preserve disclosure of information necessary for meaningful accountability while allowing appropriate redaction of personally identifiable and medical information concerning individual workers.

The Draft Incident Reporting Template should be revised to capture exposure incidents involving zoonotic pathogens carried by animals in laboratories, even when no laboratory-acquired infection is ultimately confirmed.

Specifically, the reporting template should include fields for:

*Animal species involved in the incident
*Whether the animal was imported and country of origin
*Whether post-exposure prophylaxis or precautionary treatment was administered
*Whether the exposure involved a known or suspected zoonotic pathogen
*Whether pathogen testing was conducted following the incident and the results of that testing

For the Draft Meeting Minutes Template, NIH should encourage IBCs to document discussions involving zoonotic disease risks associated with animals used in experimentation, particularly imported nonhuman

primates, and how the committee evaluated relevant zoonotic hazards and what corrective or preventive measures were considered. This information would improve NIH's ability to identify recurring risks, evaluate trends across institutions, and determine whether additional safeguards are warranted, as well as improve transparency and institutional decision making.

6. Other feedback relevant to this resource: NIH should issue additional guidance regarding zoonotic hazards associated with animals used in experiments, particularly imported nonhuman primates, when those hazards exist independently of the experiment's intended biological agent.

NIH should also ensure that its proposed National Biosafety Data and Safety Analysis Center can identify patterns involving animals used in experimentation. The draft establishes the Center to aggregate, de-identify, and analyze incident data, near misses, and anomalies. For incidents involving animals, standardized data should therefore identify the species involved and the animals' origin, as well as whether a known or suspected zoonotic agent and subsequent medical treatment were involved. This information would allow NIH to determine whether particular species, sources, or research practices are repeatedly associated with biosafety incidents.

Overall, the draft policy is a significant step toward modernizing biosafety oversight by expanding its scope beyond recombinant and synthetic nucleic acid research. But a modernized policy should evaluate a biological hazard based on the risk it actually presents, not on whether that hazard was deliberately introduced as part of an experiment. The final policy should close the adventitious-agent reporting gap, require federal reporting of consequential zoonotic exposures involving these animals, collect animal-specific information necessary to identify patterns across institutions, and preserve meaningful public access to incident and oversight information. Doing so would better align the policy with NIH's goals of accountability, transparency, and protection of public health.

More information is available on the following webpages and in the following documents:

https://www.peta.org/misc/peta-reports-and-factsheets-regarding-monkeys-imported-for-experimentation/
https://www.peta.org/wp-content/uploads/2023/02/Melioidosis_NASPHV_Notification-2.22.22.pdf
https://www.peta.org/wp-content/uploads/2026/10/2024-05-29-PETA-letter-FBI-Burkholderia-pseudomallei-introduction-via-primate-importers.pdf

377. Association of Public Health Laboratories

I am responding: On behalf of an organization

Name:

Name of Organization: Association of Public Health Laboratories

Type of Organization: Professional Organization/Association

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Association of Public Health Labs

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The current definition of biomedical research leaves some uncertainty about which activities are covered and where PHLs fall within the scope of the new policy. PHLs conduct applied research to improve testing and detection of agents of public health concern, a critical activity for effectively responding to emerging biological and chemical threats. During responses to threats such as Zika, Ebola, and global pandemics, PHLs may need to rapidly evaluate, adapt, or improve testing methods as new information and technologies become available. These activities directly support public health response efforts and should not unintentionally trigger additional research oversight requirements that could delay implementation of needed testing.
APHL recommends that NIH clarify this definition to distinguish applied research conducted as part of PHL operations from research intended to be covered by the policy, and to make it clear that PHL test development and improvements are outside the policy's scope.
PHLs may be affiliated with academic institutions, collaborate on NIH-funded research, or provide specialized testing services for research projects. In specific instances where these research collaborations fall within the scope of NIH Policy, APHL understands that PHLs' participation in the research project would be subject to the biosafety oversight requirements and assurances of NIH-regulated collaborators, where applicable. However, APHL's understanding is that these relationships would not, on their own, bring unrelated PHL diagnostic testing and applied research activities within the scope of the policy.
APHL asks NIH to confirm these interpretations and clarify any circumstances under which the policy would apply to PHLs. If certain PHL applied research activities are intended to be covered, additional information is needed on which activities would be affected and what requirements would apply, so that APHL can further evaluate how those requirements could affect PHL operations.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): APHL supports opportunities for PHLs and other laboratory sectors to voluntarily contribute to national biosafety initiatives, including the proposed National Biosafety Data and Safety Analysis Center.

APHL's Biosafety and Biosecurity Committee (BBC) has identified the need for a national approach to the collection and analysis of biosafety data. Currently, limited information is available to assess laboratory incidents and identify common risks and trends across laboratory settings. A national resource for this information would provide all laboratories with a better understanding of where safety improvements are needed and help inform risk assessments, training, and other biorisk management practices. Encouraging participation across both private and public laboratory sectors will be important to the success of this effort. Laboratories must have confidence that information shared through the Center will be handled appropriately, sensitive information will be protected, and reporting will not be used to penalize institutions. Establishing this trust will help encourage participation and the sharing of lessons learned.

APHL encourages NIH to provide opportunities for voluntary, confidential participation by PHLs and other laboratories, regardless of whether they are subject to the policy. This would allow the broader laboratory community to contribute to and benefit from national biosafety data without creating additional oversight requirements for laboratories outside the policy's intended scope.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: APHL encourages NIH to retain and emphasize the provision in Appendix G-II-C-5 that requires consultation with the public health authority for facilities conducting research involving Risk Group 3 agents with potential for societal consequences (e.g., RG3 influenza viruses, SARS-CoV/SARS-CoV-2 chimeric viruses, etc.). Public health laboratories and other public health authorities can provide important expertise on surveillance, testing capacity, preparedness, and response considerations associated with these agents. This consultation can also help ensure that potential public health impacts and the availability of appropriate tests are considered in institutional biosafety planning.

NIH should also consider providing guidance on opportunities for qualified PHL representatives to participate in or serve as subject-matter experts on Institutional Biosafety Committees (IBCs), particularly when research involves agents of significant public health concern. Greater engagement between research institutions and public health authorities could strengthen communication, support preparedness, and help ensure coordination when an incident may require a broader public health response.

6. Other feedback relevant to this resource: N/A

378. Phillip Sharp

I am responding: On behalf of myself

Name: Phillip Sharp

Name of Organization: MIT

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cell and Cancer Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The current proposed in the definition of biohazards is not based in current science. In the 50 years since the initial guidelines from NIH, there has not been a laboratory experiment that has definitively produced a sickness or a biohazard. The current guidelines has been repeatedly update and are more than adequate to protect the community. The proposed guidelines create redundant reporting and include reporting that could be unrelated to recombinant DNA. This will slow progress in a critical field of research with no obvious advantage.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Recombinant DNA and biohazards have been regulated for over 50 years by NIH. Periodic revisions of the guidelines are appropriate. These proposed guidelines are not appropriate and will increase cost and delay discovery.

3. Continued utility of Risk Groups: There are other regulatory agencies of NIH that assign Risk Groups and these risk groups are acknowledged in the BSL based guidelines. The training of personnel for experimental protocol and conditions for experimentation are also part of BSL. The BSL system does not need to be replaced by the BMBL system which expands reporting that overlap other regulatory reporting and supervision.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I expect NIH currently has a public facing Hot Line where anonymous individuals can report breeches of guidelines or the research related to the generation of biohazards. These need to be supported with an awareness campaign. If it does not currently exist there needs to be a government wide committee that integrates intelligence about dangerous activities. This includes monitoring of social media. Finally private companies should be aware that use of their services that create biohazards are a liability that should not be ignored.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: As far as I am aware, the process that generated these signifiant changes did not engage a broad sector of the actors who will be regulated by them. I do not think these proposed guidelines have gained support by the boarder community.

6. Other feedback relevant to this resource: See above.

379. Drew Fayram

I am responding: On behalf of myself

Name: Drew Fayram

Name of Organization: Merrick & Company

Type of Organization: Not Applicable

Role: Other

Role - Other: Senior Scientist and Biosafety Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): High containment laboratory science

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attachment

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attachment

3. Continued utility of Risk Groups: See attachment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attachment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attachment

6. Other feedback relevant to this resource: See attachment

Uploaded File: NIH-Biosafety-Policy-Comments.docx

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

Topic to Address*: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:
    a. the nature and stability of the genomic modification;
    b. whether the modification is heritable and the potential for transmission through breeding;
    c. effects on animal health, phenotype, host range, susceptibility, or disease;
    d. potential entry into breeding or food-production systems;
    e. potential environmental release or interaction with non-research animal populations;
    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and
    g. applicable federal, state, or other regulatory oversight.
2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

    Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

The biosafety and biosecurity community believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In an earlier response, the biosafety and biosecurity community requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, the biosafety and biosecurity community welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. The biosafety and biosecurity community does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. The biosafety and biosecurity community recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, The biosafety and biosecurity community recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with our earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. the biosafety and biosecurity community recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, the biosafety and biosecurity community kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. The biosafety and biosecurity community encourages NIH to work collaboratively with us to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While the biosafety and biosecurity community supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: The biosafety and biosecurity community recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. The biosafety and biosecurity community supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

380. Drexel University

I am responding: On behalf of an organization

Name: Sarah Archibald

Name of Organization: Drexel University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Draft_NIH_Biosafety_Response.pdf

Description: Drexel University conducted a survey, which informed the responses and recommendations.

Institutional Response from Drexel University to NIH

Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Drexel University appreciates the opportunity to provide feedback on the Draft NIH Biosafety Policy for Research Involving Biohazards. We support NIH's goal of strengthening biosafety oversight while encouraging a framework that is risk-based, practical to implement, and appropriately focused on activities that present meaningful biosafety risk. We do, however, recognize the potential for additional red tape, administrative burdens, and financial costs for both the federal government and research institutions, particularly when these requirements may not be necessary or appropriate for all federally funded research.

After soliciting input from Drexel investigators, biosafety stakeholders, and institutional compliance personnel, we provide the following recommendations and comments on the draft policy:

Key Recommendations

1. Maintain a Risk-Based Oversight Framework

Drexel strongly encourages NIH to preserve and enhance a risk-based approach to biosafety oversight. Requirements should be proportional to the level of biological risk and potential impact associated with research activity.

Specifically, NIH should:

- Differentiate oversight, reporting, and review requirements based on biosafety level, agent characteristics, and incident severity.
- Focus expanded requirements on research activities that present substantive biosafety concerns rather than broadly applying identical requirements to low- and high-risk work.
- Ensure that reporting thresholds are calibrated to meaningful risk and do not create unnecessary reporting obligations for minor events.
- Provide additional guidance, examples, templates, and decision tools to support consistent risk assessment and mitigation practices across institutions.

2. Preserve Existing Exemptions for Low-Risk Research

Drexel is concerned that the draft policy may unintentionally expand oversight requirements for activities that have historically been recognized as low risk.

We recommend that NIH:

- Clarify treatment of historically exempt activities under the NIH Guidelines.
- Retain current exemptions for routine ABSL-1 and comparable low-risk transgenic animal activities.
- Preserve exemptions for routine colony maintenance, breeding, purchase, and transfer of qualifying transgenic or knockout rodents.
- Clearly distinguish routine animal husbandry and colony management activities from higher-risk genetic manipulation or pathogen research activities.
- Avoid imposing registration or review requirements for activities that have not demonstrated significant biosafety concerns.

Expanding review requirements for routine low-risk transgenic animal work could significantly increase administrative volume without providing a commensurate biosafety benefit.

3. Minimize Administrative Burden and Resource Impact

The proposed policy introduces several new oversight, documentation, reporting, and training expectations that will require substantial institutional and federal government resources.

Drexel recommends that NIH:

- Avoid duplicative oversight processes that overlap with existing institutional review or compliance mechanisms.
- Consider the resource implications for institutions, including the need for additional biosafety professionals, administrative support, and IBC infrastructure.
- Conduct implementation impact assessments to evaluate the burden imposed on research institutions.
- Establish clear review pathways for:
    - Administrative changes
    - Minor amendments

    - Designated member review, in lieu of synchronous FCR, following federally mandated IACUC Designated Member Review process
    - Full committee review
- Permit institutions to leverage qualified staff review and administrative screening processes where appropriate.
- Provide supplemental funding opportunities or administrative supplements to support hiring biosafety personnel and expanding IBC infrastructure.

As federal agencies simultaneously advance other biosafety and DGOF-related initiatives, institutions will likely require significant investments in personnel and compliance resources to meet new expectations.

4. Reevaluate Public Transparency and Disclosure Requirements

Drexel supports appropriate transparency but believes additional safeguards are needed to prevent unintended consequences associated with public disclosure requirements.

We recommend that NIH:

- Reassess requirements for public posting of incident reports and committee records.
- Limit public reporting requirements to incidents with significant impacts to biosafety or public health.
- Permit redaction of:
    - Personal information
    - Medical information
    - Proprietary research information
    - Security-sensitive information
- Provide appropriate context when reporting incidents publicly.
- Consider aggregated reporting approaches for low-severity incidents and near misses.

Without appropriate context, public reporting may inadvertently generate confusion or mischaracterization of routine laboratory incidents that pose little or no public risk.

5. Clarify Definitions, Scope, and Policy Applicability

Several areas of the draft policy would benefit from greater detail and clarity to promote consistent implementation across institutions.

Drexel recommends that NIH provide additional clarity regarding:

- Definitions of covered biohazards and genetically modified organisms.
- Gain-of-function and related terminology.
- Applicability of policy requirements to NIH-funded and non-NIH-funded activities.
- Reporting thresholds and expected timelines.
- Available exemptions and exclusions.
- Expectations for institutional risk assessment processes.

Improved clarity would help institutions achieve consistent interpretation and compliance while reducing administrative uncertainty.

6. Preserve Effective Existing Biosafety Programs

Institutions have invested considerable effort in developing robust biosafety oversight programs under the current framework.

Drexel encourages NIH to:

- Build upon existing institutional biosafety systems rather than replacing effective processes.
- Maintain flexibility that allows institutions to tailor oversight to their research portfolios and organizational structures.
- Recognize the range (or breadth) of activities conducted at research universities, including research, teaching, clinical, and community-engaged programs.

7. Improve Incident Reporting Requirements

Drexel supports standardized reporting but believes additional clarification is needed.

NIH should:

- Develop a comprehensive reporting decision matrix.
- Provide clear definitions for:
    - Confirmed exposure
    - Potential laboratory-acquired infection

    - Containment failure
    - Containment loss
    - Minor spill
    - Near miss
- Distinguish events requiring:
    - Immediate NIH notification
    - IBC review only
    - Internal institutional management
- Clarify:
    - 24-hour notification triggers
    - 30-day reporting requirements
    - Expectations for incomplete investigations
    - Reporting responsibilities during uncertain or evolving situations

8. Provide Adequate Implementation Time

The proposed transition may require substantial institutional changes.

Drexel recommends:

- At least 12 months between publication of final guidance and full implementation.
- Availability of templates, guidance documents, and reporting systems prior to implementation.
- A phased adoption process that includes:
    - Program inventory
    - Training
    - Staffing adjustments
    - Assurance development
    - System modifications
    - Transition of existing protocols

- Preservation of existing renewal cycles where possible.

A phased implementation approach will facilitate compliance while minimizing disruptions to ongoing research.

Conclusion

Drexel University supports NIH's efforts to modernize biosafety oversight and strengthen stewardship of research involving biohazards. We encourage NIH to ensure that the final policy remains risk-based, clearly defined, operationally feasible, and supported by appropriate institutional infrastructure. Particular attention should be given to preserving exemptions for low-risk activities, clarifying scope and reporting requirements, establishing clear institutional accountability, protecting sensitive information in public disclosures, and providing sufficient implementation time for institutions to successfully transition to the new framework.

A policy grounded in proportional risk, clear guidance, and practical implementation will strengthen biosafety while supporting the continued advancement of biomedical research.

381. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definitions are too broad and go way beyond the intentions and scope of the intentions in this policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Use of Risk Groups should continue to be used even when genetically modified since they are rated by risk. Risk can be assessed and changed depending on genetic modification, but the assumption is that no modification will result in a dangerous gain of function or increase the risk assessment of the agent, so RG1 agents should not be included in the scope of this document.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Policy-Comments.pdf

DGOF Listed Outcomes:

1. Enhance harmful consequences of a biological agent*
    a. The definition of biological agent is… “all biological agents and biologically derived toxins capable of causing death, disease, or harm in a human, animal, plant, or other living organism; deterioration of food, water, air, equipment, supplies, or material of any kind; or deleterious alteration of natural resources.”
    b. I feel like this should not include anything at RG1 given the definition of RG1 agents, “Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community.”
    c. While I understand the concern about modification of agents, I feel like there should be more emphasis on the intent/purpose of the modification rather than the action of genetically modifying an agent itself. There are many standard and completely harmless genetic modifications that researchers make regularly to make the work feasible and efficient.
2. Disrupt beneficial immunity or immunization against the biological agent
    a. Of course, we do not want to disrupt immunity in any way, but there should be some room for nuance when it comes to model development since otherwise research is not able to move forward in many cases.
3. Confer prophylactic or therapeutic resistance or evade detection methodologies
4. Increase stability, transmissibility, or ability to disseminate the biological agent
    a. Of course, we do not want to increase transmissibility or stability, but there should be some room for nuance when it comes to model development since otherwise research is not able to move forward in many cases.
5. Alter host range or tropism of the biological agent
    a. Again, see above comments on model development for the purpose of research.
6. Enhance the host-population susceptibility to the biological agent
    a. Again, see above comment.
7. Generate or reconstitute an eradicated or extinct biological agent

Dangerous Gain-of-Function (DGOF) research

- There should be a clear list of exemptions including standard genetic modifications made to biological agents for the purpose of making research logistically feasible.

Grant Proposal Decision Path and Order:

- All federal grants should increase their award time to account for the extra burden of time and effort required to get through the new screening processes so that workflow is minimally impacted.
- Federal review should be a transparent process with a clear and consistent timeline so that researchers can ensure that they have funding to maintain their lab.
- Allocate extra money in each grant for the maintenance of new IRE committees and to compensate the extra work of the ICDGOF

List of Entities of Concern

- There should be a grace period built into this to consider ongoing research in collaboration with entities that might not have previously been of concern
- Depending on the severity of "concern", there should also be some flexibility on the extent of involvement with said entities

What is in Scope?

- Things that are non-pathogenic should not be in the scope of the guidelines
- Why is the breeding of transgenic animals a concern? Or should it be the breeding of
- 'Plasmids' is too generic – the type of plasmid should be specified
- Why are all, "cells, viruses, or organisms that have been genetically modified," considered a biohazard? I would think that this should be more specific about whether these cells, viruses, etc can cause harm AND are genetically modified. It should also take into consideration what kind of genetic modification has been introduced.
- Why are well-characterized cell lines in scope?

The definition of genetic modification should include a list of common laboratory modifications that do not confer any harmful phenotypes

Incident Reporting:

Extent of "first aid" treatment required regarding RG1/BSL-1 incidents should be specified since some BSL-1 labs have desks in the lab and could get unrelated low risk injuries

382. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Parasitology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I do not believe the scope of the new policy is appropriate for the goal of the modernization of the policy. My interpretation of the proposed changes to the scope is that it would actually widen the scope to include things that are not actually a biohazard. According to wording of point 2 of the scope, any genetically modified mouse line could fall under this or any non-infectious bacterial expression vector could fall under this. Furthermore, the wording under gene modification referring to "have the potential for one or more cycles of replication in a cell; or can be transcribed or translated" could again now include non-biohazard research. For example, under this it could be assumed that expressing a plasmid in competent cells is now considered a biohazard. I understand there is a fine line between keeping the scope broad to avoid it being too narrow, however, as it reads now the scope is too narrow and should really be clarified.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I do not see any issues with this.

3. Continued utility of Risk Groups: I do not see any issues with this.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Before pushing voluntary compliance, the scope should really be clarified.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I appreciate the effort to streamline incident reporting and meeting minutes via a template. I am supportive of these templates and that they need to be public facing for transparency as they would create consistency with reporting. However, I am against that PI information would be public facing and not redacted. I understand having accountability for incidents, however, a policy like this will guarantee that PI's no longer report incidents for fear of backlash. The policy should not be publicly doxxing PIs for reporting incidents, that information should be redacted from public facing documents.

6. Other feedback relevant to this resource: N/A

383. University of Oregon

I am responding: On behalf of an organization

Name: Bethany Jenkins, Vice President for Research & Innovation

Name of Organization: University of Oregon

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): The UO is an R1 research institution with a broad biomedical research portfolio.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached response letter

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached response letter

3. Continued utility of Risk Groups: See attached response letter

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attached response letter

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached response letter

6. Other feedback relevant to this resource: See attached response letter

Uploaded File: RFI-response-biosafety-2026.pdf

Description: Institutional response letter attached

UNIVERSITY OF OREGON

Monday, October 19, 2026

RE: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards

To Whom it May Concern,

The University of Oregon (UO) appreciates NIH's efforts to modernize and strengthen biosafety oversight and supports the overall goals of enhancing biosafety, transparency, accountability, and public trust in the biomedical research enterprise. We agree that biosafety oversight frameworks should evolve alongside advances in biotechnology and increasingly complex research environments.

At the same time, we encourage NIH to provide substantially greater implementation guidance, clearer policy language, and a more realistic implementation timeline before finalizing the policy. Several aspects of the draft would create significant operational and administrative challenges for institutions without corresponding resources, staffing support, or implementation mechanisms. Our comments focus on the practical requirements for implementing the proposed framework at UO.

1. Clarify Applicability to Existing Research and Expectations for Institutional Assurances

One of our most significant concerns is the transition of ongoing research to the new policy. The draft policy states that it would apply to all existing awards and agreements as of the effective date and would prohibit covered research from being conducted until NIH has approved the institution's written Biosafety Assurance submitted through its Authorized Organizational Representative (AOR).

It remains unclear whether an institution must review and revise all existing Institutional Biosafety Committee (IBC) registrations and approvals prior to submitting such an assurance for NIH approval. If full compliance requires reassessment of all currently active protocols before the effective date, institutions will face a substantial implementation burden that is not adequately addressed in the proposal.

For institutions such as the UO, where IBC review processes, registration forms, and risk assessment procedures were developed under the existing NIH Guidelines framework, determining compliance with a fundamentally revised policy could require extensive protocol review and modification. We recommend NIH explicitly state:

- Whether existing IBC approvals remain valid until their next scheduled review;
- Whether institutions may implement the policy prospectively for new submissions while transitioning existing protocols over a defined period;
- What minimum actions are required before an AOR may submit an institutional Biosafety Assurance for NIH approval; and

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The University of Oregon is an equal-opportunity institution committed to cultural diversity and compliance with the Americans with Disabilities Act.

- Whether institutions will be afforded a phased implementation process, including transition arrangements for institutions awaiting NIH approval of their Assurances.

Given the breadth of changes proposed, the six-month implementation period appears insufficient, particularly if institutions must reassess active research portfolios before certifying compliance. We recommend an implementation period of at least 12 months after complete operational guidance and Assurance procedures are available, with a phased transition of up to 24 months for currently approved protocols.

2. Better Align Institutional Responsibilities with Available Resources

The draft policy would expand or modify existing institutional biosafety responsibilities and introduce additional implementation requirements. In addition to requiring institutions to ensure appropriate training regarding laboratory safety and implementation of the policy, the draft assigns responsibilities to IBCs and biosafety personnel, including:

- Periodic review of approved research;
- Development and maintenance of emergency response plans;
- Incident review and documentation;
- Implementation of revised public posting requirements for meeting minutes and incident reports;
- Expanded record-keeping obligations;
- Additional risk assessment activities; and
- Potentially broader oversight responsibilities under the expanded scope of covered biohazards.

At the UO, implementation would rely on one Biosafety Officer within Environmental Health and Safety and on IBC members who already have substantial responsibilities. Revising active registrations, institutional procedures, training materials, and public-facing resources within six months would place substantial demands on this existing capacity. Even where obligations already exist, changes in scope, documentation, reporting, and public posting would require substantial institutional work. The draft does not provide sufficient operational guidance regarding staffing, implementation funding, or the resources needed to support these requirements.

We recommend NIH:

- Provide detailed implementation guidance documents before policy implementation;
- Develop standardized training materials that institutions may adopt;
- Create model templates and best-practice resources beyond those currently proposed;
- Consider supplemental implementation funding opportunities; and
- Establish a proposed timeline for a transition period during which institutions can develop the necessary infrastructure.

We request that the final policy clarify how responsibilities should be allocated among the institution, the IBC, the BSO, and PIs, including which activities may be delegated and what documentation is required to demonstrate appropriate oversight. The final policy also needs to

distinguish de novo protocol renewal from periodic compliance monitoring, and clarify the expected frequency, acceptable delegated processes, and documentation for the latter.

It would be beneficial if the NIH would provide practical examples and eligibility criteria for delegated review of well-characterized, low-risk research so that institutions can apply the policy consistently and proportionately.

3. Provide Greater Specificity Regarding Training Requirements
The policy requires institutions to ensure appropriate training for IBC members, Biosafety Officers, investigators, and laboratory personnel, and assigns PIs responsibility for training personnel under their supervision. However, the draft does not specify sufficient operational detail regarding:

- Minimum training expectations;
- Frequency of required training;
- Acceptable training formats;
- Required documentation standards; or
- Whether NIH will provide nationally standardized curricula.

Without such guidance, institutions may develop substantially different interpretations and implementation approaches, undermining the goal of consistency across the research enterprise. We strongly encourage NIH to provide detailed implementation standards and standardized training resources before compliance is required.

4. Recognize the Significant Administrative Revisions Required at Institutions
While the draft policy is intended to modernize oversight, implementation will require extensive revision of institutional processes and documentation.

At the UO, the existing IBC registration process already incorporates a robust risk assessment framework. Nevertheless, substantial revisions would be needed to:

- Modify and restructure IBC registration forms;
- Update biosafety manuals and program documentation;
- Revise institutional policies and procedures;
- Update investigator guidance materials;
- Develop new training programs;
- Create new incident-management and reporting workflows; and
- Adapt and maintain public-facing resources to meet revised transparency requirements, including changes to existing meeting-minutes posting practices.

These efforts represent a major institutional undertaking that extends beyond simple policy adoption. NIH should acknowledge the scale of these changes and provide both implementation guidance and sufficient time for institutions to make the necessary operational modifications.

5. Request Additional Guidance Before Policy Becomes Effective

The draft policy states that NIH intends to provide supplemental implementation materials and guidance resources. We appreciate NIH's existing explanatory resources and request additional operational guidance addressing unresolved implementation questions.

Because many key operational details remain unclear, institutions cannot accurately estimate compliance obligations, staffing needs, training requirements, or implementation costs. We therefore recommend that NIH:

- Release draft implementation guidance concurrently with the policy prior to finalization;
- Expand FAQs to address the transition of active protocols, Assurance submission and approval, delegated review, training documentation, and reporting and redaction procedures;
- Conduct webinars and stakeholder engagement sessions focused on implementation;
- Establish a formal transition process; and
- Set the effective date to allow at least 12 months of preparation after complete operational guidance and Assurance procedures are available, with a phased transition of up to 24 months for currently approved protocols.

We support transparency and request clear guidance on permissible redactions and the preparation of public-facing records that protect personal privacy, proprietary information, and security-sensitive details.

The University of Oregon supports NIH's goal of strengthening biosafety oversight and appreciates the agency's investment in modernizing a framework that has served the research community for decades. However, the current draft raises significant concerns regarding implementation feasibility, administrative burden, institutional resource requirements, and the ambiguity surrounding compliance obligations for ongoing research activities.

We respectfully request that NIH provide greater clarity regarding expectations for existing protocols, expand implementation guidance, and adopt a longer and more phased implementation timeline. These modifications would better enable institutions to achieve the policy's important biosafety objectives while maintaining effective and sustainable research oversight programs.

Sincerely,



Bethany Jenkins
Vice President for Research and Innovation

384. American Physiological Society

I am responding: On behalf of an organization

Name: Mark Eichelberg

Name of Organization: American Physiological Society

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Science Policy

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Physiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft NIH biosafety policy significantly expands the scope of the current NIH Guidelines on Research Involving Recombinant or Synthetic Nucleic Acid Molecules. As a result, Institutional Biosafety Committees (IBCs) will be responsible for oversight and reporting for a much broader range of research.

The key concern over this expansion in scope is that it will likely result in IBCs devoting more bandwidth to low-risk research activities, leaving less time to evaluate higher-risk research. Institutional policies already often empower IBCs to exercise oversight of research involving the types of biohazards included in the draft NIH biosafety policy. However, the draft policy would formalize this oversight and potentially increase administrative burden by requiring reportable and auditable protocol reviews and incident reports, even for low-risk research activities.

While the option for delegated review of lower-risk research somewhat offsets the administrative burden of the new policy, NIH could further reduce the administrative burden without significantly compromising safety by making a small number of changes to the policy, such as 1) extending IBC protocol approval to five years to match the duration of most NIH research project grants; 2) removing the requirement to publicly post incident reports for lower-risk incidents that do not significantly endanger public health; and 3) generally streamlining reporting requirements for low-risk and routine research activities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed policy outlines three tiers of covered research based on risk. However, the regulatory oversight required under the draft policy is broadly similar among the tiers. All research protocols, regardless of risk tier, must be evaluated by the IBC and included in meeting minutes, although the lowest risk tier allows delegated review. Similarly, safety incidents during research at all risk tiers must have a report published on a public-facing webpage, although the lowest risk tier does not require reporting to the NIH.

While it is a strength of the policy to divide research into tiers of risk, the policy could be improved by streamlining lower-risk research oversight. This should include removing the requirement of posting low-risk incident reports to a public-facing website. This requirement does not improve safety, but it discourages reporting of incidents and places potentially sensitive information at risk. Further feedback about this requirement is given in the response to question 5.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The level of detail included in the Required Template for Meeting Minutes and the Required Template for Reporting Incidents and Accidents, in combination with the requirement that they are posted to a publicly viewable webpage, compromises research and information security, conflicts with federal research security regulation, and provides no meaningful benefit to laboratory safety. It would create a standardized and searchable set of data across institutions detailing experimental procedures, agents and species used, and where they are kept.

Federal policies and regulations require institutions to safeguard information about potentially dangerous agents and provide oversight of their storage and record-keeping. For example, 42 CFR § 73.17 requires that records and databases of select agent inventories have controlled access. The standardized meeting minutes template conflicts with this and other regulation by creating a public list of agents and locations along with details about security and containment. Allowing specific information to be redacted from the meeting minutes will not resolve this issue, as it is unreasonable to expect IBC members to reliably judge which information may be potentially sensitive.

Beyond the information about select agents and potentially dangerous material, the detail requested in the meeting minutes template effectively creates a full list of protocols on an institution's website. This significantly compromises research security by providing a road map for competing laboratories to reconstruct unpublished work. In particular, researchers in countries of concern could use this information to gain an advantage over the U.S.

The information required in the Draft Incident Reporting Template creates a clear conflict between safety and personal privacy that likely undermines the policy's effectiveness. The template requires including the name of the Principal Investigator for the research conducted while the individual(s) involved in the incident are identified only by position title rather than by name. However, for many researchers in academic laboratories with a small number of staff, deducing an individual from their title and PI name is often trivial. As a result, online incident reports will create a public record detailing incidents that can with minimal effort be traced to the individual(s) involved.

One concerning outcome of this policy is that it encourages laboratory staff and PIs not to report biosafety incidents. If either the staff member or the PI is concerned about the potential consequences of making a laboratory accident a matter of public record, they may conceal critical information about the accident from the IBC. The draft biosafety policy provides no opportunity for anonymous reporting of safety concerns or incidents, so every report requires the release of potentially identifying information.

Both the Required Template for Meeting Minutes and the Draft Incident Reporting Template create public records of detailed information about animal research. Research involving animals is sensitive and researchers targeted by activist groups often receive harassment and threats of violence. The incident report template makes information about which researchers handle which animal species publicly available, creating a map for activist groups to target researchers.

It is unclear how requiring institutions to publicly post the details required in the meeting minutes and incident report templates would advance laboratory safety. However, for the reasons outlined here, this requirement conflicts with research security, exposes sensitive information, and weakens oversight of laboratory safety reporting. NIH should amend the proposed policy so that requirements to publicly disclose information do not conflict with federal research security regulations and limit detailed information about research protocols, agent storage, animal research, and researcher identities. Additionally, the NIH policy should facilitate anonymous incident reporting to IBCs so that safety issues can be addressed without placing individuals at risk.

6. Other feedback relevant to this resource: NIH should provide examples of the level of detail required (and not required) for protocol reviews for both high-risk and low-risk categories of research, including a rubric for determining which risk category an investigator's research falls under.

385. Trent Peacock

I am responding: On behalf of myself

Name: Trent Peacock

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical and infectious disease research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Scope:
For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:
-the use of biohazards within this context is ill-defined, too broad, and requires more precision (i.e., healthy human adults (BMBL), healthy human children, toddlers and infants, immunocompromised human adults, children, toddlers and/or infants, drawing a blood sample as part of an IRB and IBC research protocol (is it now covered under the OSHA rule, the NIH, the BMBL or any combination thereof)
-is it the intent of the policymakers to isolate human health risk and research to the NIH and OSHA, agricultural health risk and research to USDA-APHIS and BRS, and select agent risk and research to the CDC?
-would it not be easier to use the existing OSHA, FSAP and USDA-APHIS frameworks, since by the proposed definition of biohazards, the current policy scope is redundant and will now cause confusion amongst researchers and compliance offices?

Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
-concur, however as previously stated this aspect of the policy, as is, becomes redundant when compared to the FSAP regulations
-what immune status of "humans"?
Cells, viruses, or organisms, other than plants, that have been genetically modified;
-is "organisms" the intended target word, as from a biological perspective it will include humans, animals, fungi, parasites, etc. (except plants)
-are "organisms", as outlined, all biohazardous
-natural or synthetic genetic modification
Toxins, prions, and other self-aggregating proteins; or
-chemical and toxins of biological origins?
Cells or organisms, other than plants, containing 1, 2, or 3 above.
-see previous statements

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Research with wild type or genetically modified RG2 biological agents for which lower containment is requested vs. Research involving RG2 wild type biological agents
-the first requires full IBC review prior to initiation and the second can be by delegation prior to initiation
-recommend that they should be combined and delegated review should be an option available to the local IBC
-if they cannot be combined, what is the reason?

3. Continued utility of Risk Groups: Both should be used when generating a biological risk assessment, as their definitions are different but complementing.
-a RG1 agent, which is not covered under this policy and when grown in large batch volumes, should be done so at a higher BSL due to more stringent containment requirements

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): A mechanism of public/community recognition, of the institution, by the NIH.
An tiered implementation procedure that is tailored to the institution with the assistance of the NIH.
An NIH pre and post implementation assessment.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: What level of detail is required for the Training and Risk Assessment portion of the Meeting Minutes template? An example or rubric of what the expectations are would go a long way in preventing a cycle of submissions and resubmissions.

Forms either need to be fillable or with an expanded narrative section or both. An example or rubric of what the expectations are would go a long way in preventing a cycle of submissions and resubmissions.

6. Other feedback relevant to this resource: Implementation timeline should either be extended, tiered, tailored to the individual institution or some combination thereof. It is unrealistic and, if enforced immediately, will result in confusion, deterioration of trust and/or failures of continued compliance amongst compliance offices, researchers and institutions.

An immediate announcement regarding continued institutional operations based on current NIH Guidelines or the revised policy following the termination of the comment period. It seems unreasonable for institutions to begin a laborious process/program improvement task, only to have to change it again due to policy revisions.

A tiered implementation rubric and milestone implementation plan/guidance based on institution size (i.e., number of covered laboratories, BSL, agent types, etc.), levels of funding, types of research, etc. would be helpful in streamlining implementation and providing markers for institutional leadership and the NIH regarding implementation status updates.

386. The Manton Center for Orphan Disease Research at Boston Children's Hospital

I am responding: On behalf of an organization

Name: Alan H. Beggs, PhD

Name of Organization: The Manton Center for Orphan Disease Research at Boston Children's Hospital

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Genetics and genomics of pediatric disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The current definition of "Genetic modification" is inaccurate and inappropriate. As proposed is specifies:

Genetic modification:
The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
Have the potential for one or more cycles of replication in a cell; or
Can be transcribed or translated

The final criterion "Can be transcribed or translated> should be eliminated because that includes many transient assays that do not lead to genetic modification and would inflate the scope of experiments tremendously, leading to undue regulatory burden without any additional benefit.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

387. Kara Drolet

I am responding: On behalf of myself

Name: Kara Drolet

Name of Organization: OHSU

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Apparent lack of exemptions: It is recommended that NIH maintain the previously established categories of exempt research. NIH describes the purpose of the modernization as expanding oversight to biohazards while "removing red tape for low-risk research" and specifically asks commenters whether the proposed tiered oversight is appropriately calibrated to risk and administrative burden.

Exempt from IBC oversight is not synonymous with exempt from safe laboratory practice. Rather, it represents a determination that the incremental safety benefit of mandatory IBC oversight does not justify the administrative burden for a defined class of low-risk research. Currently exempt research was previously determined by NIH, following notice and opportunity for public comment, not to present a significant risk to health or the environment.

Review requirements for primary cell lines/well-characterized cell lines: As written, "may be contaminated" could be interpreted to include virtually any primary human or animal cells (including any research involving NHP cells or tissues) for which the infectious-agent status of the source has not been comprehensively established.

NIH should define "adventitious agent," establish a risk-based threshold for determining when contamination is reasonably anticipated, and clarify whether donor screening, testing, source information, or other documentation can establish that primary cells do not fall within this category. The Policy should also clarify its application to commercially obtained cells, repository specimens, patient-derived cells, and primary animal cells and provide examples of included and excluded materials. A merely theoretical possibility of contamination should not independently trigger IBC oversight; the definition should be tied to a known or reasonably anticipated potential hazard to human health. Clear criteria are necessary to avoid additional administrative burden by unnecessarily expanding IBC oversight beyond research presenting a meaningful biosafety risk

The Policy does not provide sufficiently objective criteria for determining when a cell line qualifies as

well-characterized, creating the potential for inconsistent interpretations among investigators, biosafety professionals, and IBCs. NIH should specify what level of information regarding identity, provenance, biological characteristics, and adventitious-agent testing is necessary; whether established commercially available or widely used cell lines may be presumed to satisfy the definition; and how primary, immortalized, genetically modified, and patient-derived cells should be treated. NIH should also provide examples of included and excluded cell lines. Because this determination may affect the scope and level of institutional oversight, a clear, risk-based definition is necessary to ensure consistent implementation and avoid additional administrative burden by unnecessary review of research that does not present a meaningful biosafety risk.

Review requirements for self-aggregating proteins: IBC review is appropriate for the review of research involving prions or biospecimens identified to be from a person or animal known to have a prion-based disease. However, the term self-aggregating is not sufficiently defined to permit institutions or investigators to determine consistently if every protein that happens to aggregate or contributes to an aggregation-associated human disease, such as ALS, is also covered.

Protein aggregation alone does not necessarily establish a meaningful biosafety hazard. NIH should clarify whether “other self-aggregating proteins” is intended to encompass proteins with prion-like, seeding, propagation, transmissibility, pathogenic, or other specified hazard characteristics rather than any protein capable of aggregation. The definition should identify objective criteria and provide examples of both covered and excluded materials.

Human subjects' studies requiring IBC review:
Section IV-2 outlines the only clinical research provision and specifically identifies IBC review for biohazards that shed, replicate, integrate, require higher-risk manipulation, or involve RG2 or higher wild-type agents. There is no discussion of other genetically modified agents being used in clinical research, such as plasmids or RNA, and no discussion of exemptions. Given the federal initiative to streamline clinical trials: https://www.hhs.gov/press-room/hhs-launches-clinical-trials-reform-initiative.html, additional administrative burden should not be introduced by expanding IBC oversight in the clinical research arena.

The Policy should also exempt any covered clinical research studies from mandatory three-year de novo IBC review or permit an administrative continuation process confirming that no material changes affecting biosafety have occurred. Full IBC review should be required only for clinical research presenting local biosafety risk, where there may be questions regarding product handling and possible shedding. This approach would maintain appropriate biosafety oversight while reducing unnecessary regulatory burden

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: It is recommended that NIH revise the approach to public posting of incidents so that detailed incident reports are submitted to NIH but are not routinely required to be posted publicly in their entirety. Alternatively, NIH could provide a template for public posting of standardized, de-identified high level summary information of incidents that might include root-cause categories and corrective actions. NIH could separately require disclosure of additional information when a particular incident presents a compelling public health or safety interest.

This approach balances transparency objectives with the equally important need to preserve a just, non-punitive reporting culture in which researchers and staff are encouraged to report incidents, near misses, and potential safety concerns promptly and completely. It also provides protections for researchers that are increasingly threatened or harassed due to the tools or subject matter of their research.

Importantly, NIH would receive the information necessary to evaluate significant incidents, institutional responses, and compliance. The distinction would therefore be between information necessary for regulatory oversight and information necessary for public transparency, rather than assuming that the same level of detail is needed for both purposes.

6. Other feedback relevant to this resource: Overall implementation and requirement for institutional assurance: A six-month implementation period is insufficient given the breadth, complexity, and institutional impact. Revising electronic systems to accommodate the new regulations is a significant challenge that will likely prevent many institutions' ability to meet this timeline. Additionally, updating policies and procedures and ensuring that researchers have the training they need to understand the new requirements, including newly covered areas of research, will require additional time. The time required to identify newly covered research is one reason why it is critical for entities to be held to realistic and achievable implementation timelines.

NIH should provide a detailed description of the required elements of an institutional assurance and publish accompanying implementation guidance before policy adoption, including model assurance language, implementation templates, and sufficient lead time for institutions to develop. Administrative burden should be kept in mind in considering required elements.

Delegated review: It appears that it is the intent that an initial protocol may qualify for delegated review if it only contains work identified as eligible for delegated review under Section IV-3. Clarified wording is recommended "for minor amendments to previously approved submissions or for initial research protocols"

There are inconsistencies between the descriptions of research that require committee review (Section IV-2) and research that may be eligible for delegated review (Section IV-3). A potential clarification is to state that "Where research is described by both Section IV-2 and Section IV-3, research meeting all applicable criteria specified in Section IV-3 may undergo delegated review unless another characteristic of the research independently requires review under Section IV-1 or IV-2. A delegated reviewer may refer any submission to the full IBC when warranted based on the risk assessment."

388. Advarra, Incorporated

I am responding: On behalf of an organization

Name: Stephanie Pyle

Name of Organization: Advarra, Incorporated

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Other

Role - Other: Regulatory Documentation Manager

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: see attached

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): see attached

3. Continued utility of Risk Groups: see attached

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): see attached

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: see attached

6. Other feedback relevant to this resource: see attached

Uploaded File: NOT-OD-26-112-NIH-Draft-Biohazards-Policy_Advarra-response-vFinal.pdf

Description: Comments by Advarra Inc. on NOT-OD-26-112 Request for Information: Draft NIH Biosafety Policy for Research Involving Biohazards

6100 Merriweather Dr., Suite 600
Columbia, MD 21044
410-884-2900

Date: October 19, 2026

To: National Institutes of Health Office of Science Policy

Subject: Comments on NOT-OD-26-112 Request for Information: Draft NIH Biosafety Policy for Research Involving Biohazards

Submitted electronically via NIH comment form at https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

Dear National Institutes of Health (NIH) Office of Science Policy (OSP),

Advarra, Incorporated (Advarra) is a U.S.-based company that provides institutional review board (IRB) and institutional biosafety committee (IBC) research review and oversight services, compliance and quality assurance services, inspection readiness and auditing, and technology platforms in support of clinical research operations. In particular, Advarra externally administers IBCs for over 1,500 research sites, including large academic medical centers, small academic institutions, privately owned clinical research sites, biotech companies, and drug manufacturers. With our experience in applying biosafety standards to the clinical realm, Advarra has published on the evolution of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) as it relates to clinical research as well as the applicability of Food and Drug Administration (FDA) Guidance documents to IBC review.[1-5]

Advara applauds the NIH's efforts at modernizing biosafety oversight, including the agency's commitment to soliciting input from stakeholders representing the public and the biosafety community. We are pleased to provide comments and suggestions on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice No. NOT-OD-26-112) issued by the NIH in August 2026.

As a general comment, we note there are potential gaps and ambiguities in the draft policy regarding clinical research. Specifically, Section IV-2 outlines criteria for higher risk clinical research that requires IBC review and approval prior to initiation; however, the draft policy does not explicitly address lower risk clinical research. This absence of granularity regarding lower risk research could be interpreted in one of two ways: Either research involving biohazards (i.e., lower risk clinical research) will not be covered by the draft policy's IBC requirement, or most clinical research involving lower risk biohazards could be reviewed via IBC subcommittee / designated member review (DMR) or could be determined to be exempt from IBC review.

The latter could be very helpful, as DMR would allow flexibility and streamlining of the review process based on a given research study's level of risk. However, those relying on the former interpretation may

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assume most research involving biohazards would not require IBC review, which could lead to significant safety and regulatory oversight gaps in the clinical setting.

A recent peer reviewed survey article suggests biosafety professionals overwhelmingly support the unique role of IBCs in addressing biosafety considerations that are not fully encompassed by FDA for regulatory oversight. Greater than 90% of respondents stated that the guidance provided by IBCs to research personnel is important for product handling procedures, training and education, as well as needlestick and exposure prevention. While the article's authors acknowledge their limited pool of survey respondents as a potential source of bias in their methodology, we feel strongly that even if the data were obtained from a larger survey group, the results would reach similar conclusions.[6]

Our observations and comments below provide suggestions for the NIH to consider when revising the draft policy for research involving biohazards. Where we suggest specific content revisions, we use ***bold-italicized font*** to indicate new or revised text.

1. Scope of research covered by the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.

Observation 1. While the "Scope" discussion in Section II of the draft policy explicitly covers certain aspects of clinical research in laboratory settings involving biohazards, other aspects of clinical research appear to be only partially addressed or missing. This limited description of the research covered under the draft policy could lead to an inadvertent gap in safety and regulatory oversight for clinical research. For additional information on this concern, please see our general comment, which begins on p1 of this response document.

We also note that non-scientific regulatory personnel at pharmaceutical companies which also collaborate with the NIH routinely misinterpret the current NIH Guidelines as not applying to RNA-based technology, specifically misunderstanding the "can be translated or transcribed" criteria in Section III-C-1-2-d. This also creates a gap in safety and regulatory oversight for clinical research, as RNA technology can be used both for low-risk applications (e.g., mRNA-based vaccines) as well as higher risk activities (e.g., guide RNA for CRISPR-based gene editing). This higher risk category would also include replicons / self-replicating RNAs, which can potentially cause prolonged gene expression, and mRNA-encoded hazardous products (e.g., toxins, oncogenes, prions, or other self-aggregating products capable of causing neurodegenerative disease).

Suggestion 1. Because of the exposure risks to research participants, we suggest NIH explicitly state that IBC review is required for products covered under the scope of the policy when administered to one or more human research participants. This would include products containing nucleic acid molecules that have either undergone genetic modification (e.g., viral vectors, gene-modified cellular therapies, etc.) or are capable of introducing genetic modifications (e.g., stable gene integration, gene editing, epigenetic changes, etc.) into human research participants, as outlined in the draft policy's definitions.

We also recommend revising the definition of "genetic modification," in Section II "General Definitions," to clarify that the definition applies to RNA-based technologies. See below for specific revision recommendations, where we suggest adding additional information to Section II "Scope" and "General Definitions":

Scope

For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:

1. Wild type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;
2. Cells, viruses, or organisms, other than plants, that have been genetically modified;
3. Toxins, prions, and other self-aggregating proteins; or
4. Cells or organisms, other than plants, containing 1, 2, or 3 above.

[NEW] IBC review is required for products covered under the scope of the draft policy when administered to one or more human research participants.

[text omitted]

General Definitions

[NEW] Genetic modification:

- The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria:
    - Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or
    - Have the potential for one or more cycles of replication in a cell; or
    - Can be transcribed or translated ***(e.g., RNA-based technology)***; or
- The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means.

Please also refer to Observation 6 / Comment 6 in this document related to the assignment of risk with clinical research and IBC review.

Observation 2. Section IV "Categories of Oversight for Research Based on Risk" states certain research associated with higher levels of risk or uncertainty must be reviewed and approved at the federal level by NIH. In this section, the draft policy also states that such research must also be reviewed and approved by the IBC. However, in Section IV-1 of the draft policy, we note a potential omission or inconsistency in the described approval requirements. Specifically, the first sentence of Section IV-1 describes review and approval for higher risk research to be obtained from NIH alone. Later, in the last sentence of Section IV-1, initiation of research may proceed from both NIH and the IBC. Given Section IV's statement that review and approval must be obtained from both NIH and the IBC, we are unsure why "IBC" is omitted.

Suggestion 2. We suggest NIH clarify if IBC review and approval does or does not apply in Section IV-1. If the "IBC" omission in the first sentence is inadvertent, we propose revising the first sentence in Section IV-1 as follows:

> ***[NEW]*** Review and approval for determination of appropriate containment and biosafety practices and procedures must be obtained from NIH ***and the IBC*** for higher risk research including:

Observation 3. In Section IV-2 of the draft policy, we note that the clinical research elements included in the bulleted list reflect higher risk products but are not labeled as such.

Suggestion 3. For improved clarity, we suggest NIH revise the sixth bullet in the Section IV-2 list to add "Higher risk" in front of "clinical research":

> - ***[NEW] Higher risk*** clinical research involving deliberate administration to one or more human research participants of the following biohazards:

Observation 4. In the current NIH Guidelines, Section III-C-1-2-a pertains to clinical research involving recombinant or synthetic nucleic acid molecules that "Contain more than 100 nucleotides." This detail is quite helpful for IBCs, as there is a large volume of low-risk clinical research involving agents under 100 nucleotides that would not benefit from IBC review. However, the draft policy does not include information on agents below 100 nucleotides.

Suggestion 4. In Section II "Scope," we recommend the draft policy include an exemption for clinical research involving nucleic acid molecules under 100 nucleotides in length that are not capable of creating durable genetic modification, including genomic integration or gene editing, and do not encode toxins, oncogenes, prions, or self-aggregating products capable of causing neurodegenerative

disease in human or animals. We propose the following language for NIH's consideration, which we suggest could be included as new content in Section II "Scope" situated after the current penultimate sentence "Based on . . . oversight as described in Section IV.":

> ***[NEW] Exempt from this policy is research involving the delivery to one or more human research subjects of nucleic acid molecules, that contain under 100 nucleotides and:***
>
> - ***Are not capable of creating durable genetic modification, including genetic integration or gene editing, and***
> - ***Do not encode functional portions of toxins, oncogenes, prions, or self-aggregating products capable of causing neurodegenerative disease in humans or animals.***
>
> ***The exemption does not apply to use of viral vectors, gene modified microorganisms, or other agents covered by this policy. Delivery of guide RNA for gene editing requires IBC review and is not covered under this exemption.***

Observation 5. The current NIH Guidelines apply to NIH-funded or -supported research and also extend to research collaborations. We respectfully request NIH to reconsider the draft policy's narrower approach and expand it to include research conducted or collaborated with non-federally funded organizations. We note this because there is currently no requirement under FDA regulations at Title 21 to require biosafety review for clinical research involving biohazards. An external obligation or similar mechanism (like the current NIH Guidelines) for research collaborations is valuable to help ensure that the entire research community applies appropriate safeguards and oversight to this type of high-risk research regardless of a project's funding source. In addition, since the draft policy has expanded beyond the current NIH Guidelines' scope of use with recombinant or synthetic nucleic acid molecules, we recommend the draft policy incorporate revised language addressing this type of research.

Suggestion 5. In the draft policy's Section II "Compliance and Enforcement," we suggest NIH include wording similar to that provided in the current NIH Guidelines Section I-C-1-a-(2) "General Applicability." We suggest the following proposed language be added as the new second paragraph in "Compliance and Enforcement":

> ***[NEW] This policy applies to research that involves testing in humans of biohazards, including materials capable of genetic modification covered under the scope of this policy and developed with NIH funds, if the institution that developed those materials sponsors or participates in those projects. Participation includes research collaboration or contractual agreements, not only provision of research materials.***

2. Structure of tiered oversight (i.e., Federal, institutional, and investigator), including appropriateness in terms of calibration to risk, accountability measures, transparency, and streamlining of administrative burden, etc.

Observation 6. The level of review and approval by the IBC required for clinical research is not solely delineated based on risk in the draft policy, which presents potential inconsistency with the risk-based approach used throughout the rest of the draft policy to categorize and delineate types of research that would or would not require IBC review. Specifically, we notice this inconsistency in Section IV-2 of the draft policy:

> - Clinical research involving deliberate administration to one or more human research participants of the following biohazards:
>   - Products that are capable of shedding, replicating, or integrating.
>   - Products that require higher risk manipulations (e.g., aerosolization, bladder infusions).
>   - RG2 or higher wild type biological agents (e.g., challenge experiments for medical countermeasures).
>
> Clinical research cannot be initiated until IBC, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

Suggestion 6. We suggest NIH revise the draft policy to add information regarding clinical research risks and provide the following revised language for NIH's consideration. We propose placing this language in Section IV-2 after the sentence "Clinical research cannot be initiated until . . . have been obtained.":

> ***[NEW] Clinical research involving lower risk agents and manipulations may be reviewed as outlined in Section IV-3. Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members. Clinical research falling into this category would include agents that have undergone genetic modification rendering them unlikely to cause human disease and/or are not capable of shedding, replicating, gene editing, or genomic integration.***
>
> ***When the level of IBC review is not clearly outlined in this policy, refer to Section V-D. Requirements and Considerations for Risk Assessment of Manipulations of Biohazards.***

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Observation 7. Risk group classifications (such as those in the current NIH Guidelines Appendix B - Table 1 "Basis for the Classification of Biohazardous Agents by Risk Group") are an essential first step in the risk assessment process, and we encourage NIH to retain this approach in the policy. However, we note that the current risk group classification criteria in the current NIH Guidelines Appendix B - Table 1 are inadequate for agents which are not microorganisms (e.g., biological toxins, gene editing technology, gene drives, or any recombinant or synthetic nucleic acid molecules which are not in microorganisms, or use of lipid nanoparticles to deliver biological materials).

Suggestion 7. We suggest NIH include in the draft policy the Appendix B - Table 1 content from the current NIH Guidelines, potentially placing it in the draft policy's Section V-A after the first paragraph. We also recommend updating these risk group classifications to reflect the types of agents utilized in biomedical research beyond wild type microorganisms. For assistance regarding risk classification of agents that are not wild type organisms, NIH might consider adapting the methodology from the Rand Corporation's *A Standardized Framework for Assessing High Risk Life Sciences Research* Appendix A, "Detailed Methodology for Assessing Laboratory Risks Versus Research Benefits."[7]

4. Effectiveness of compliance and enforcement mechanisms for ensuring biosafety, including strategies for encouraging voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions), and addressing any biosecurity challenges.

Observation 8. The draft policy appropriately identifies IBCs, IRBs, and institutional animal care and use committees as important components of the biomedical research regulatory oversight system. We suggest the final biosafety policy build on that concept by explaining how IBC and IRB review should be aligned across internal and external review committees when research involves the administration or other clinical use of a biohazardous product.

This alignment is especially important for FDA-regulated investigations involving products that may shed, replicate, or integrate; contain genetically modified material; require higher risk procedures; or otherwise create biosafety risks for research participants, healthcare personnel, laboratory staff, or the surrounding community.

Section IV-2 of the draft policy identifies as requiring prior IBC review clinical research involving products capable of shedding, replicating, or integrating; products requiring higher risk manipulations; and certain wild type biological agents. These provisions are important. However, the draft policy addresses research primarily through NIH funding requirements and institutional assurances. As a result, it may not consistently apply to FDA-regulated clinical investigations involving biohazards conducted by sponsors or institutions that do not receive NIH funding. Further, confining rigorous federal biosafety mandates to NIH-funded or -supported research alone creates a patchwork system of oversight, leaving privately funded, industry-sponsored, or foundation-sponsored research operating under inconsistent standards. To truly safeguard public health and national biosecurity, the final policy

should establish a universal baseline for all biomedical research involving biohazards nationwide, aligning federal expectations across the entire research ecosystem.

This approach creates a gap in oversight of research involving biohazards. FDA's investigational new drug regulations require IRB review and approval for clinical investigations, but 21 CFR part 312 does not expressly require a sponsor or investigator to identify, obtain, or maintain IBC approval when an investigational product or protocol presents a biosafety concern. A clinical investigation involving biohazards and human participants could therefore be subject to FDA requirements for IRB oversight without also being subject to the current NIH IBC framework if the institution does not receive NIH funding or otherwise fall within the scope of the draft policy.

Suggestion 8. NIH could use this draft policy development process to work with FDA on a consistent framework for coordinating IRB and IBC oversight of FDA-regulated clinical research involving biohazards.

One possible model is found in 21 CFR 361.1, which governs certain types of radioactive drug research. That regulation requires both:

1. Review and approval by an FDA-approved Radioactive Drug Research Committee (RDRC); and
2. Review and approval by an IRB that satisfies the requirements of 21 CFR part 56.

The two committees have separate responsibilities. The RDRC evaluates issues related to radioactive drug and radiation exposure, while the IRB evaluates the protection of human research participants. Neither committee replaces the other. The regulation also establishes reporting relationships, including requirements concerning adverse reactions and communications with FDA.

NIH and FDA could consider a comparable IRB and IBC review structure for clinical research involving biohazards. In this framework, IRB and IBC review functions would remain separate and distinct, and would not require either committee to make determinations outside its area of expertise. The framework would ensure that:

- Each committee can determine when review by the other is required;
- Both committees receive the information necessary to conduct their respective reviews;
- Approval status is documented and available to the other committee; and
- Relevant decisions, protocol changes, incidents, and safety information are communicated in a timely manner.

Should NIH consider such an approach, we recommend that this be included in any future final policy. The policy would also clarify the respective areas of responsibility. For a clinical study, IBC review would focus on biosafety matters such as containment, product administration, shedding, replication, integration, potential environmental release, occupational exposure, and response to accidental

exposure. The IRB would remain responsible for evaluating the rights, safety, and welfare of human research participants under 21 CFR part 56.

This approach would preserve the distinct expertise and authority of IRBs and IBCs while ensuring that the two oversight systems are connected when a clinical investigation under 21 CFR 312 presents biosafety concerns.

5. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Observation 9. Statements specific to clinical research are distributed throughout the draft policy, rather than organized as a single discussion specific to clinical research. Without a dedicated section specific to clinical research, we are concerned research professionals may miss certain nuances or requirements for this type of research.

Suggestion 9. We suggest NIH create a dedicated section in the draft policy that specifically discusses clinical research considerations, including those identified in Suggestions 1-8 above. Organizing clinical research-specific considerations together, in one place, will aid investigators and research teams in better understanding and satisfying their biosafety obligations when conducting biohazards research with human participants. If NIH chooses to include a dedicated section on clinical research, we suggest this section would supersede the suggested clinical research placement locations described above. This clinical research section might appear as a sub-section under Section IV and could include the following proposed language:

> ***[NEW] Section IV-4. Clinical Research Involving Administration of Biohazards Including Materials Capable of Genetic Modification to One or More Human Research Subjects***
>
> ***IBC review is required for the deliberate administration of products covered under the scope of this policy to one or more human research participants. This includes products containing nucleic acid molecules that have either undergone genetic modification (e.g., viral vectors, gene modified cellular therapies, novel agents or organisms, RNA-based technologies, etc.) or are capable of introducing genetic modifications (e.g., stable gene integration, gene editing, epigenetic changes, etc.) into human research participants, as outlined in the policy's definitions.***
>
> ***For initial submissions of research within the scope of the policy, and not otherwise specified in other sections, review and approval must be obtained from the IBC before initiation. This would include:***
>
> *[continued on next page]*

[continued from previous page]

- ***Higher risk clinical research involving deliberate administration to one or more human research participants of the following biohazards:***
  - ***Products that are capable of shedding, replicating, gene editing, or integrating.***
  - ***Products that require higher risk manipulations (e.g., aerosolization, bladder infusions).***
  - ***RG2 or higher wild type biological agents (e.g., challenge experiments for medical countermeasures).***

Clinical research cannot be initiated until IBC, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

Clinical research involving lower risk agents and manipulations may be reviewed as outlined in Section IV-3. Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members. Clinical research falling into this category includes agents that have undergone genetic modification rendering them unlikely to cause human disease and that are not capable of shedding, replicating, gene editing, or genomic integration.

Exempt from this policy is research involving the delivery to one or more human research participants of nucleic acid molecules that contain under 100 nucleotides in length and:

- ***Are not capable of: creating durable genetic modification, including genomic integration or gene editing, and***
- ***Do not encode functional portions of toxins, oncogenes, prions, or self-aggregating products capable of causing neurodegenerative disease in human or animals.***

The exemption does not apply to use of viral vectors, gene modified microorganisms, or other agents covered by this policy. Delivery of guide RNA for gene editing requires IBC review and is not covered under this exemption.

When the level of IBC review is not clearly outlined in this policy, refer to Section V-D. "Requirements and Considerations for Risk Assessment of Manipulations of Biohazards."

Clinical research involving handling and administration of potentially biohazardous materials to research participants is most often conducted in clinical settings that do not conform to laboratory BSLs. However, precautions to protect personnel must include the use of standard precautions such as gloves, and eye and respiratory protection.

Observation 10. We note the draft policy expressly requires IBC review and approval before initiation of clinical research involving deliberate administration to human research participants of products capable of shedding, replicating, or integrating; products requiring higher-risk manipulations, including aerosolization or bladder infusion; or Risk Group 2 or higher wild type biological agents.

As discussed in Observation 8 above, the draft policy does not establish a comprehensive reference to gene therapy clinical research as a distinct category for purposes of biosafety oversight and review. Nor does the draft policy consider that many viral vectors, gene-edited products, genetically modified cellular therapies, and certain other gene therapy products may shed, replicate, integrate, or require higher-risk administration, which in our opinion would fall under the types of clinical research involving deliberate administration to human research participants as listed in the draft policy.

Suggestion 10. We recommend NIH clarify how the draft policy applies to clinical research involving gene therapy products, genetically modified cellular products, genome-editing products, viral and nonviral vectors, genetic vaccines, and RNA-based technologies. Although Section IV-2 identifies clinical research involving products capable of shedding, replicating, or integrating, the draft policy does not define these terms or provide a product-specific framework for determining when IBC review is required.

NIH could provide definitions, examples, and a decision framework addressing at least the following:

- In vivo and ex vivo gene-therapy products;
- Viral vectors, replicons, and nonviral delivery systems;
- Genome editing products and whether editing constitutes integration;
- Proliferation of administered cells and whether it constitutes replication;
- Transient detection, persistence, and shedding;
- Products with replication-defective or replication-competent components; and
- The appropriate endpoint for IBC oversight when biosafety risks may continue after administration of the final dose.

Observation 11. In the second sentence of the penultimate paragraph of Section V-E, the draft policy uses the phrase "universal precautions," which we understand to be an outdated term that the U.S. Centers for Disease Control and Prevention (CDC) replaced with the term "standard precautions" in 1996.[8]

Suggestion 11. We recommend NIH revise Section V-E to replace "universal" with "standard" in the second sentence of the penultimate paragraph in this section:

[REVISED] However, precautions to protect personnel must include the use of ***standard*** precautions such as gloves, and eye and respiratory protection.

Observation 12. Section III-A "Responsibilities of the Institution" in the draft policy proposes the requirement for an Authorized Organization Representative (AOR) to provide written assurance every four years that the institution will comply with the policy.

Suggestion 12. When an institution uses an externally operated IBC, it will need guidance on how to provide assurance for the administrative responsibilities of the externally operated IBC to maintain the IBC roster, chair name, and meeting minutes on behalf of the institution. We recommend achieving this through a reliance agreement or some form of memorandum of understanding between the external IBC and the AOR at the institution.

In closing, Advarra is grateful for the opportunity to provide NIH with our comments on the draft NIH Biosafety Policy for Research Involving Biohazards. Please feel free to contact us as we would be happy to participate in further discussion on this matter. Should NIH create any working groups or stakeholder meetings to address the comments and/or draft guidance, we are fully willing to attend and assist in this endeavor.

Sincerely,

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CC: Daniel Eisenman, Executive Director, Biosafety Services; Julie Ozier, Senior Vice President and Institutional Official, Regulatory; Jan Hewett, Senior Vice President, FDA Regulatory Advisor; Stephanie Pyle, Regulatory Documentation Manager

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389. Elyse Walk

I am responding: On behalf of myself

Name: Elyse Walk

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Biosafety Associate Director

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical research and education

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I appreciate the opportunity to comment. I support the goal of modernizing biosafety oversight and offer the following concerns about scope and definitions to improve clarity, consistency, and workability.

Toxin scope and oversight do not align. Section II covers "toxins" with no threshold, while the definition is limited to proteins or peptides that harm humans. IV-2 assigns full review to Select Agent toxins, yet the Select Agent list includes toxins that do not appear to be proteins or peptides, such as tetrodotoxin and saxitoxin. The policy should clarify whether these are covered by the Select Agent reference, the definition, or both. IV-3 allows delegated review for "biological toxin proteins not on the Select Agent list." Section V-A recognizes that risk depends on potency, amount, and form (such as isolated subunits), but none of these factors appear in the scope or review categories. It is also unclear whether inactive derivatives, toxin-encoding nucleic acids, or low-potency proteins are covered, and why peptides are defined as toxins but IV-3 mentions only proteins. Without a de minimis or potency threshold, the literal language creates significant administrative burden.

Animal hazards are treated inconsistently. Section II covers wild-type agents only if they cause disease in humans, which appears to exclude animal-only pathogens. Yet the policy covers prions that cause disease in animals, defines zoonotic agents, requires animal-containment expertise on some IBCs, requires IBC review of incidents involving research animals, and addresses ABSL containment. The threshold definition should be reconciled with these provisions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Sections IV-2 and IV-3 overlap. IV-2 assigns full IBC review to "genetically modified cells, viruses, or organisms, other than plants," without limiting this by risk group. IV-3 allows delegated review for genetically modified RG1 agents, transgenic organisms at BSL-1/ABSL-1, certain plasmids and viral vectors, and well-characterized cell lines. IV-2's introductory language ("not otherwise specified in other sections") may be meant to resolve this, but IV-2 names genetically modified organisms itself. The final policy should state explicitly

which provision controls.

Occupational health. Section III-A says an institution "may be required" to maintain an occupational health and safety program under other regulations, or if "needed based on research conducted," while Section III-C makes the PI responsible for explaining procedures "advised or required." The policy does not say what triggers the need, who decides, or who develops the procedures. Section V-E shows the policy can state a trigger when intended: it requires an occupational health plan for certain influenza work. IBC membership requirements also do not include occupational health expertise.

IBC composition and capacity. The animal-containment expertise requirement applies only to animals too large for primary containment isolators. Routine small-animal work at ABSL-1 to ABSL-3, which the policy also covers, triggers no expertise requirement. The draft also adds substantial IBC duties, including expanded protocol and incident review, review of lower-risk incidents, public posting of minutes and incident reports, record maintenance, and coordination of NIH approval requests. It does not give IBCs explicit authority to suspend unsafe research, accreditation or certification standards, protections for institutional independence, specific national training resources, or funding. Responsibilities should be matched with authority and resources.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reporting and public posting. Section III-B requires public posting of all incident reports after "appropriate and allowable redactions," but the Policy does not define these. The draft template does, and its standard is narrow: it requires the PI's name and prohibits redacting information available from public sources. Because the posting requirement extends to lower-risk incidents that are not reportable to NIH, this may discourage reporting, and individuals may be identifiable from position titles and timelines in small laboratories. Redaction standards should be defined in the Policy itself, with careful consideration of whether lower-risk incidents require PI identification.

IBC meeting minutes template. Section III-B requires IBCs to use the draft minutes template and to post approved minutes publicly. The template calls for a detailed narrative for each protocol (agent characteristics, sources of nucleic acid sequences, vectors, modifications, manipulations, risk assessment, protocol-specific training, occupational health review, containment level, and vote), as well as incident reviews, inspection results, IBC training, attendees, and other business, and it states that discussion of any research subject to the Policy should be captured. The draft also expands scope to all biohazards, including toxins, genetically modified cells and organisms, and primary cells, and adds IBC review of lower-risk incidents. The volume of material in each set of minutes will therefore rise substantially, particularly for committees that review many low-risk protocols. I recommend that NIH (1) specify a minimum set of required elements and let institutions set the level of detail based on risk; (2) allow concise or batched summaries of routine, low-risk protocols and delegated approvals, with full records retained for audit and available to NIH; and (3) reconcile Section IV-3, which says delegated approvals must be reported "in full" to the IBC, with the template, which says they may be attached as a list.

6. Other feedback relevant to this resource: I largely agree with much of what CSHEMA as provided in terms of implementation:
Timeline and research continuity. Section II sets the effective date six months after publication of the final Policy, and Section III-A prohibits any covered research until NIH has approved an institutional Biosafety Assurance. The draft also says NIH intends to provide implementation resources, which means they may not exist when the clock starts. In six months, institutions would need to inventory newly covered research, prepare and obtain approval of assurances, revise procedures and electronic systems, build public-posting and redaction processes, train staff, and in some cases establish new IBCs. I recommend (1) a longer phased implementation period (for example, 24 months) that begins only after the final Policy and implementation materials are released; (2) a transition mechanism, such as provisional or deemed assurances and continued validity of existing IBC approvals, so that ongoing research is not interrupted while NIH reviews assurances; and (3) piloting of the assurance, minutes, and incident-reporting templates at institutions of different sizes and resources before they become mandatory.

Implementation resources. The most useful materials would be a Biosafety Assurance template, model procedures, decision tables with worked examples for each oversight category, sample completed minutes and incident reports, clear redaction guidance, and guidance for shared or externally administered IBCs.

Training. Training is required for IBC members, BSOs, PIs, and laboratory staff, but no minimum standard or responsible training authority is established. NIH's implementation resources should address this.

Cost. The draft adds substantial new obligations without addressing funding. NIH should consider how institutions, particularly smaller ones, will cover the cost of compliance.

Thank you for considering these comments.

390. Artiom Gruzdev

I am responding: On behalf of myself

Name: Artiom Gruzdev

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Re: Request for Comment — Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)
To the Office of Science Policy:

Thank you for the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. I am a genetic engineer with 25 years of experience in the field, working in a mouse model core facility at a research institute. I am submitting these comments solely as an individual; the views expressed are my own and do not represent the position of my institution or employer.

At the outset, I want to commend NIH for undertaking this effort. The foundational Guidelines have served the research enterprise well, but a framework established roughly half a century ago was due for a thorough refresh. It is worth recalling that the original recombinant DNA requirements arose in the 1970s, long before the advent of PCR or the development of gene targeting in the mouse genome. They were written for a scientific landscape that no longer describes much of today's work. In that era, viral means of transgenesis posed a genuine health concern for laboratory staff, a concern that is simply not present in the non-viral gene editing performed today. Modernizing biosafety oversight so that it keeps pace with how science is actually conducted, and with the actual risks it presents, is both overdue and welcome, and I appreciate the care and extensive community engagement that have gone into this proposal.

My comments are narrow and concern a single category of research: the generation of genetically modified mouse models by non-viral methods. By this I mean techniques such as single-cell CRISPR injection into embryos and the editing of mouse embryonic stem cell lines to derive novel mouse lines from edited stem cells. I want to be clear about what I am not addressing. I am not arguing against IBC oversight of in vivo viral work, which involves vectors capable of replication or transmission and presents

genuine biosafety considerations that an IBC is well suited to review. My comments are confined to non-viral germline modification of mice, where no infectious agent and no replication-competent vector is involved, and where the only product of the work is a novel mouse.

Existing expert oversight already covers this work comprehensively. The draft policy would bring non-viral generation of genetically modified mouse lines within IBC review (as delegable review under Section IV-3). At my institution, this activity is already subject to a layered structure of oversight by subject-matter experts. A dedicated committee reviews the generation of all new genetically modified mouse models. The Institutional Animal Care and Use Committee oversees all maintenance and crossbreeding of those models. And the IBC already works closely with the IACUC to oversee all in vivo viral use. Adding a further IBC review for the non-viral generation of mouse models would duplicate oversight that competent, specialized bodies already provide, creating administrative burden without a corresponding gain in safety. This runs counter to the draft's own stated aim of removing red tape for low-risk research and streamlining administrative burden.

IBCs should remain focused on their core mission. An IBC's central purpose is to protect human safety and to weigh societal and environmental impact. That mission is best served when the committee's finite attention is directed to the activities that actually implicate it. Non-viral generation of genetically modified mouse models does not. The techniques at issue carry such a low probability of any adverse event that routine IBC review of them does not advance human safety; it diverts committee time and expertise away from the higher-risk work where that scrutiny matters most. Layering oversight onto this category risks diluting, rather than strengthening, the IBC's effectiveness.

The uncertainty inherent in novel models does not justify added oversight, because the ceiling on plausible harm is so low. I want to address directly what might seem like a counterargument. It is true that generating a novel mouse model often produces an animal whose exact phenotype cannot be fully predicted in advance; knocking out a gene can yield genuinely novel biology, and the precise consequences are frequently unknown until the animal is characterized. Asking an IBC to anticipate those consequences in advance is, in a real sense, a Sisyphean task. But the relevant question for biosafety oversight is not whether an outcome is uncertain; it is whether a plausible worst-case outcome poses meaningful risk. For a non-virally generated genetically modified mouse, even the worst-case scenario presents a negligible hazard to laboratory staff, to other mice, or to society at large. A mouse carrying an edited genome is not infectious, is not transmissible to humans, and is maintained under existing animal-care controls. Where the upper bound on harm is this low, additional layers of oversight would slow the pace of science without producing any measurable improvement in either safety or the quality of the research.

The scale of this activity, and the draft's treatment of crossbreeding, illustrate the burden concretely. At my institution alone, we maintain nearly 1,000 different combinations of genetically modified mouse lines across varying genetic backgrounds. In a typical year, roughly 150 new mouse crosses are generated and about 150 are retired. This work is overseen by the IACUC, which is appropriate, because it largely represents the crossbreeding of existing, already-characterized mouse lines; this is an animal-husbandry activity rather than the introduction of any new genetic material or agent. As drafted, however, the policy's scope implies that the crossbreeding of genetically modified mice would fall to the IBC. Routing

an activity of this volume and this low risk through IBC review would impose a substantial and recurring administrative load with no attendant safety benefit, and it illustrates precisely why institutions need flexibility in how this category of work is overseen.

Recommendation. I respectfully recommend that the final policy afford institutions the flexibility to assign oversight of the non-viral generation of genetically modified mouse models to an appropriate institutional body other than the IBC, rather than requiring IBC review in every case. The aim is not to remove this work from oversight, but to allow it to be reviewed by the body best suited to the task. At my own institution, for example, a dedicated committee already reviews the generation of all new genetically modified mouse lines and has the specialized expertise to do so effectively. Permitting an institution to designate such a committee, in coordination with its IACUC and with the IBC retaining jurisdiction over any work involving replication-competent or transmissible agents, would preserve rigorous, expert oversight while avoiding duplicative review and keeping the IBC's attention on the higher-risk work it is uniquely positioned to assess. This approach would be fully consistent with the tiered, risk-calibrated structure the draft seeks to establish and with its recognition of institutional oversight as a foundational pillar.

Thank you for considering these comments and for your continued work to modernize biosafety oversight in a way that is both rigorous and proportionate.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

391. Association for Research in Vision and Ophthalmology (ARVO)

I am responding: On behalf of an organization

Name: Salewa Akintilo

Name of Organization: Association for Research in Vision and Ophthalmology (ARVO)

Type of Organization: Professional Organization/Association

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Eye and vision research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: ARVO-NIH-Biosafety-Policy-Comments-October-19-2026.pdf

The Association for Research in Vision and Ophthalmology
ARVO.org

October 19, 2026

Jay Bhattacharya, MD, PhD
Director
Office of the Director, National Institutes of Health
1 Center Drive MSC 0122
Bethesda, MD 20892

RE: Comments on Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112

Submitted electronically to the NIH Office of Science Policy

Dear Director Bhattacharya:

The Association for Research in Vision and Ophthalmology (ARVO) appreciates the opportunity to comment on the National Institutes of Health (NIH) Draft Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112). ARVO is an international scientific society of vision and ophthalmology researchers whose members investigate biological mechanisms, develop and validate research models, and translate discoveries into approaches to prevent vision loss and improve eye health.

ARVO supports strong biosafety protections, responsible institutional oversight, transparency, and NIH's objective of modernizing a framework developed around recombinant and synthetic nucleic acid research. We also welcome the proposal's stated commitment to reducing unnecessary oversight for lower-risk work. However, we believe the final policy must define covered activities and risk thresholds with sufficient precision so routine research does not face burdens disproportionate to the actual biological hazards it may present.

Vision research draws upon animal and human-derived models, including genetically modified mice and zebrafish, human donor ocular tissues, primary retinal and anterior segment cells (e.g., lens, trabecular meshwork and cornea), stem-cell retinal organoids, and gene delivery platforms. These methods are not interchangeable, and relevant biosafety risks depend on the material, experimental manipulation, route of exposure, containment, and documented source characteristics, not simply on the type of model used.

Scope and Risk-Proportionate Review (Sections II and IV)

The proposed policy influences biohazard research conducted at institutions that receive NIH support even when individual projects are supported by other sponsors. NIH should clarify how this institutional reach applies to privately supported studies, collaborations, shared facilities, and storerooms, and state authorities when applicable. The policy should identify how institutions may rely on other appropriate federal oversight, and explain which activities qualify for delegated rather than full IBC review. NIH should provide practical examples for common vision-science methods (and other methods as appropriate), including low-risk genetically modified animals, human-derived cells, and nonreplicating gene delivery systems. A genetic modification or variant should not alone be treated as a proxy for a significant human-health hazard.

Primary Cells and Adventitious Agents (Section IV-2)

We are particularly concerned by the proposal to require IBC review of "primary cells that may be contaminated by adventitious agents." Without definitions or an articulated risk threshold, this phrase could be interpreted to capture a broad array of primary human and animal cells and tissues where the absence of every possible agent has not been conclusively demonstrated. Such an interpretation could include donor-derived retinal tissue, retinal pigment epithelial and corneal cells, patient-derived ocular materials, and nonhuman primate cells or tissues used in vision research. Some sources and specimens warrant significant precautions, but a merely theoretical possibility of contamination is not a sound basis for

uniform full-committee review. Additionally, the eye banks that provide donor eyes are already under strict regulation by federal agencies for infectious agents due to corneal transplants.

NIH should clearly define “adventitious agent,” distinguish known or reasonably anticipated hazards from hypothetical possibilities, and clarify how donor screening, testing, specimen provenance, supplier documentation, handling conditions, and exposure pathways inform risk assessment. Guidance should also specifically address commercial primary cells, storeroom materials, patient-derived specimens, and primary animal tissues, including nonhuman primate materials, for which risks may differ significantly by species and source. NIH should provide examples of included and excluded materials, explicitly permit documented institutional assessment or delegated review when risk is low, and require screening and source documentation to inform a comprehensive biosafety assessment.

This clarity is especially important given NIH’s priority of human-based research methods and the shift to New Approach Methodologies (NAMs). Ambiguous treatment of primary cells could slow adoption of organoids, tissue-based disease models, and other NAMs without a demonstrated, materially significant safety benefit.

Animal Models and Complementary Institutional Oversight

Genetically modified mice and zebrafish are also essential tools for understanding retinal development, inherited and age-related retinal degenerations, glaucoma, dry eye disease, optic nerve injury, and visual recovery. Where hazards are well characterized and containment is appropriate, institutions should follow streamlined, risk-based pathways. Shared documentation, coordinated review, and clear responsibility for biosafety versus animal-welfare determinations can preserve safeguards while avoiding ongoing reviews that delay research. The final policy should also distinguish routine husbandry incidents from events presenting a meaningful biosafety concern.

Human-Derived Models, Gene Delivery, and Translation

Investigators use human retinal organoids, induced pluripotent stem-cell-derived systems, gene-edited cell models, and viral or nonviral delivery tools to study disease and develop potential therapies. The oversight process should reflect whether a material is infectious or can replicate, whether manipulation materially changes risk, and what exposure is plausible. NIH should publish examples for commonly used appropriately characterized paths and cell systems to enable delegated review for activities with minimal risk. Consistent expectations across institutions and any approved international collaboration are especially important for collaborative, multisite studies and emerging researchers.

Transparency, Incident Reporting, and Research Security (Section III)

ARVO supports meaningful transparency, but public posting of IBC minutes and incident reports requires practical safeguards for personnel privacy, unpublished work, proprietary methods, facility security, and sensitive information. NIH should specify standardized redaction criteria and permit summaries when detailed disclosures do not advance public understanding. Incident thresholds should distinguish significant biosafety risks from minor, contained events addressed through local processes. Reporting should encourage prompt disclosure and institutional learning, not discourage internal reporting or invite misleading interpretations of routine laboratory events.

Implementation, Compliance, and Continuity (Sections II–V)

The proposed six-month implementation period is insufficient for institutions to revise policies, expand IBC capacity, train personnel, and align oversight across funding sources, especially with the other concerns outlined above still needing to be addressed. NIH should consider realistic administrative burden, operational cost, and implementation estimates and provide model procedures, templates, examples, training, and a phased implementation path that gives institutions more time to implement the proposal safely and effectively. Enforcement of the policy should be calibrated to actual risk profiles of the research pathways, impact severity, and remediation. Isolated and minor procedural issues should not automatically threaten unrelated NIH-supported vision research and the students, personnel, and patients who depend on its continuity.

Recommendations

1. Define “adventitious agent” and establish clear, reasonably anticipated human-health risk thresholds for primary cells, with examples across human and animal sources.
2. Provide explicit delegated or streamlined review pathways for appropriately characterized low-risk primary tissues, cell models, genetically modified animals, and delivery systems.
3. Clarify policy reach across funding sources and institutional collaborations and recognize appropriate existing federal, state, and institutional oversight.
4. Coordinate IBC review with other requirements without duplicative documentation or ongoing approvals where responsibilities are distinct, and risks are well characterized.
5. Set consistent disclosure, redaction, and incident-reporting standards that support accountability without compromising research security or mischaracterizing minor or routine events.
6. Publish practical implementation tools and allow a phased, longer transition informed by realistic institutional staffing, costs, and readiness, while addressing the concerns above.
7. Use risk-proportionate enforcement and corrective-action opportunities, protecting unrelated ongoing NIH awards from disproportionate disruption.
8. Additional clarity and guidance are also needed on whether this policy will apply retroactively to existing cells collected before policy implementation that have been safely used in research, and on any unique requirements for those existing collections, understanding the additional burden and threat the policy may have on existing research with those collections.

Conclusion

ARVO supports an effective and modern biosafety policy that protects research personnel and the public while sustaining important science. We encourage NIH to revise the draft to ensure that oversight requirements are clearly defined, proportional to reasonably anticipated risks, and workable across animal- and human-based systems that advance vision research. We welcome continued engagement with NIH leaders as NIH continues to develop the final policy and necessary accompanying guidance.

Thank you for the opportunity to provide comments.

Sincerely,

[redacted]

Iris M. Rush, CAE
Executive Director
Association for Research in Vision and Ophthalmology (ARVO)

392. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The significant concerns in these comments and raised by the broader scientific community demonstrate that the draft Policy cannot be implemented in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.
a. The stated intention of this policy proposal is to expand the scope of the NIH Guidelines while removing red tape for low-risk research. The goal of removing red tape for low-risk research within this Policy has not succeeded. The Draft Policy includes within its scope multiple categories of research that are currently Exempt in the NIH Guidelines. For example, research with certain transgenic rodents and certain recombinant work with non-pathogenic E. coli; the NIH Director has already determined that these experiments are of such low risk that they were actively designated as Exempt, yet this Policy considers them of high enough risk to require IBC approval. The Policy does not provide reasoning for this change in the risk assessment.
b. A meaningful administrative burden with the NIH Guidelines is the pathway through which NIH OSP will assign a biocontainment level for research with an agent that does not have an assigned RG within Appendix B. This issue could be less burdensome if NIH OSP had been granted authority within the Guidelines to assign a risk group to agents that do not have risk groups.
i. The current approval pathway is limited to the specific PI at a specific entity. Therefore, other PIs at the same entity are similarly required to obtain a biocontainment level from NIH OSP for the same agent.
ii. We recommend that the Policy clearly state that determinations of risk group and/or recommended biosafety levels will apply to all researchers and all entities subject to the Policy.

1. We understand that there will be differences in the recommended biosafety level due to geography/climate and considerations for research being performed outside the US, which should be considered if this recommended change is made to the Policy.
c. The Scope of the Policy states “Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained.”
i. This statement must be clarified. We appreciate that the Policy seeks to avoid duplicative oversight from multiple federal agencies. However, the statement itself is unclear regarding the oversight, approvals, and clearances that are mentioned.
1. If a researcher is registered to work with wildtype Nipah virus (RG4, therefore falling under Section IV-2) with the Federal Select Agent Program (FSAP), do they not need to obtain IBC approval for the same work?
2. If a researcher is registered to generate chimeras of paramyxoviruses within a Nipah virus backbone (a novel agent by the current definition, therefore falling under Section IV-1) with FSAP, do they need to obtain NIH and IBC approval for the same work?
3. If an incident occurs in a BSL3 or BSL4 that involves a Select Agent for which the researcher is registered with FSAP, does the incident get reported to NIH and posted on a public facing website?
d. Effective Date
i. The Policy states that the effective date will be 6 months from publication of the final Policy. This is a very short timeline to implement a Policy with such significant expansions in scope. Implementation of this Policy will require that IBCs ask for more resources from their institutions, obtain those resources, communicate with stakeholders, develop new training, implement training for IBC members and researchers, obtain new software or update software, and make significant choices in how to implement each part of the Policy. Six months is not nearly sufficient, and all entities will struggle.
ii. This is further complicated by the need to provide a written Biosafety Assurance that has been approved by NIH in order to perform any research after the effective date. Will NIH have the required full-time employees (FTEs) to review and approve hundreds of Biosafety Assurances that will be submitted within that effective date?
iii. We recommend that the effective date be at least 2 years.
e. The Policy uses terms and words but does not define them. The failure to define these words will lead to ambiguity in the interpretation and implementation of the Policy, leading to unintentional noncompliance. Further, some of these words did not have definitions in the NIH Guidelines and therefore this is a good opportunity to rectify this issue. These include:
i. Adventitious agent, organism, transgenic, GDMO, incident, release, potential risk to human health, peptide, shedding
1. Organism is inconsistently used within the Policy and is not an easily defined word. Replace “organism” with more appropriate and easily definable terms throughout the Policy. Specify bacteria, fungi, archaea, protists, viruses, or animals as needed. If there is a concern about a biological agent that doesn’t fall within those terms, be clear about that (e.g., a biological agent created through synthetic biology that cannot be readily categorized).
f. The Policy omits a review workflow for biological agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL yet cannot reasonably fall within the definition of “emerging, novel, or zoonotic agents”. This is a crippling issue for agents that are currently handled at BSL1 or BSL2, though is also an issue for agents handled at BSL3 and BSL4.

i. Theoretically, these could fall within Section IV-1 (research that requires NIH and IBC approval before initiation). However, the administrative burden on NIH to adequately review this work in a timely manner would be significant (even ignoring the administrative burden on researchers and IBCs to review this work). Additionally, much of this research cannot reasonably fall under the category of "higher risk research", when even research involving RG3 or RG4 wild-type biological agents requires only IBC review in the Policy.
ii. For example, human metapneumovirus, non-polio enteroviruses, human parainfluenza virus 5 (Orthorubulavirus mammalis), and Sendai virus (Respirovirus muris) are not emerging, novel, or zoonotic agents. Yet they lack a risk group in the NIH Guidelines and are not mentioned in the BMBL. Will NIH review be required for research with these agents for every entity and researcher that falls in scope of the Policy? If so, how many FTEs will NIH be hiring to accomplish timely reviews?
iii. How will human or animal microbiota be treated in this review workflow? Will research with every member of Bacteroides, Bifidobacterium, Akkermansia, Ruminococcus, Prevotella, and Anaerococcus require NIH review? If so, will a researcher even be able to collect a human or animal sample without being in noncompliance with the Policy?
g. The Policy does not define who has the authority to designate the risk group of an agent.
i. This is of particular importance with RG1 biological agents, since the Policy explicitly states that wild-type RG1 biological agents are outside the scope of the Policy.
ii. If the local IBC will have the authority to designate the risk group of an agent, that needs to be stated in the Policy.
iii. If the NIH will have the authority to designate the risk group of an agent, that needs to be stated in the Policy. In addition, NIH must publish and regularly update the list of biological agents that it designates at different RGs.
h. Responsibilities of the Institution (Section III-A), related to records retention
i. The Policy states "The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states "the recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report." (emphasis added).
ii. The Policy assumes that all IBC records are for projects that are federally funded. The Policy has failed to consider projects that are not federally funded and therefore will never submit a final financial report. As written, such IBC records may never be disposed of, which is either an oversight or regulatory overreach. This language must be changed to account for IBC records related to non-federally funded projects.
i. Responsibilities of the IBC (Section III-B), related to approval period
i. The Policy states "Approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required."
1. The Policy fails to describe how biosafety or biosecurity is increased by limiting research approvals to three years. Researchers continue projects over years and decades, and these projects rarely include changes that significantly increase the risk assessment.
2. Requiring a specific time frame for approvals is overly burdensome and regulatory overreach. Requiring such a short approval time will greatly increase the administrative burden of the IBC and the researcher for little to no increase in biosafety.
3. We recommend that this statement be removed from the Policy.

4. If the statement cannot be removed from the Policy, we recommend that the Policy explicitly permit grandfathering of previously approved IBC protocols that have approval periods of greater than three years.
j. Responsibilities of the IBC (Section III-B), incident reporting
i. The Policy does not define "incident" or "release". We recommend the following definitions:
1. Incident: A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.
2. Release (Loss of containment or occupational exposure): Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
ii. The Policy does not define "improper disposition" and throughout this section relies on ambiguous phrases such as "any incident", "loss of containment", "significant problems", and "minor spills … generally do not need to be reported". Terms like "first aid" and "medical treatment" should be aligned explicitly with OSHA standards.
k. Responsibilities of the NIH (Section III-D)
i. The Policy does not state which person or office within NIH will be responsible for these items. In comparison, the NIH Guidelines clearly delineated the responsibilities of the NIH Director and the responsibilities of the NIH Office of Science Policy.
1. Entities can reasonably expect that the response times for the NIH Director and for NIH OSP will be significantly different. Further, NIH OSP is staffed with many subject matter experts, while the NIH Director can never be an SME for every aspect of biomedical science. Therefore, the Policy must clearly state who will be responsible for these duties.
2. We recommend that the Policy clearly state which person or office is responsible for the duties described in this section.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): 2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).
a. In general, the tiered oversight is appreciated. The IACUC-style review that specifically permits delegate approval will be a helpful decrease to time commitments from the full IBC for review of lower risk research.
i. The Policy has replaced two previous categories of review, those requiring NIH Director approval (III-A) and those requiring NIH OSP approval (III-B), with a singular category that requires NIH approval. The Policy does not describe which person or office within NIH will be performing the review and approval of research within Section IV-1. This must be clearly stated in the Policy within the Responsibilities of NIH (III-D).
b. General Definitions: Emerging agent or organism
i. The Policy does not state who determines that an agent is an emerging agent. Does the local IBC decide what qualifies as an emerging agent? If not the local IBC, we recommend that NIH develop rapid dissemination notices that are sent to all entities identify emerging agents so that entities can avoid noncompliance.
ii. The Policy does not describe how an agent or organism goes from being an emerging agent to a non-emerging agent. Will an agent be "emerging" until the first time NIH has reviewed it under Section IV-1? Until it has been assigned a risk group? Until it has appeared in the next edition of the BMBL?
iii. Does the definition of an emerging agent include a well characterized agent that exhibits a change in pathogenicity or transmission? If this Policy existed at the time, would the recent outbreaks of Zika virus,

mpox virus, and Andes virus qualify as “emerging”? Would the label of emerging apply to the agent, or merely to the specific strain of the biological agent?
iv. If considered now (October 2026), which agents would qualify as “emerging”? Highly pathogenic avian influenza virus H5N1? SARS-CoV-2?
c. General Definitions: Genetic Modification
i. This definition is so expansive that it causes internal contradictions within the Policy.
ii. The definition uses the undefined word “organisms”, which is unhelpful. As written, this causes the Policy to confusingly regulate research conducted with genetically modified organisms (Section IV-2) differently from transgenic organisms (Section IV-3) but does not define the difference between the two. We recommend replacing the word organism with the biological agent(s) that are intended to be within scope of the Policy.
iii. Can be transcribed or translated: as written, this will include expression from an RNA vaccine that is administered to an animal or transfected into a cell line. The Policy does not describe how including this as a genetic modification addresses a biosafety concern.
iv. The introduction … of stable alterations into the genome by passaging, reassortment, chemical or radiological means: as written, the definition includes unintentional alterations into the genome, such that researchers will become noncompliant with the Policy almost immediately.
1. Passaging any virus in tissue culture will result in unintentional alterations into the genome.
2. Cancer research includes work with antineoplastic drugs that would fall within scope of this definition.
3. We recommend that this definition be re-written to be limited to intentional stable modifications.
d. General Definitions: Toxin
i. The definition of toxin could be greatly improved.
ii. For example, ISO35001 uses “substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants. This includes substances and materials, natural or as a result of biotechnology, that may contain toxins, any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance.”
1. The definition should not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (e.g., sensitizers).
2. Later in the Policy, when defining the Category of research, would be the appropriate time to limit the scope of which toxins fall under the Policy (e.g., Research with protein or peptide toxins not on the Select Agent list and with an LD50 of less than 100 micrograms per kg body weight.)
e. Section IV-1 (Research that Requires NIH and IBC Approval Before Initiation): Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL.
i. Emerging and zoonotic agents:
1. For those whose research focuses on the identification of new biological agents, the Policy offers no regulatory path to work with these agents. Once identified as an emerging or zoonotic agent with no risk group or biosafety level recommended in the BMBL, the research must be approved by NIH. However, without the ability to work with the agent, the researcher cannot generate the data required for NIH to conduct the risk assessment.
2. Without the ability to perform this research, US researchers will stop performing this work. It will then fall to international researchers to spearhead this work, leaving US researchers lagging behind.
3. We recommend that a clear approval pathway is described in the Policy to allow researchers to generate the data required for a risk assessment. This would best be performed by the local IBC.

ii. Novel agents:
1. The definition of novel agents includes chimeras. Many researchers generate chimeras (especially within a family of viruses) to study the basic biology of these agents; in these cases, the representative family member or the parental agents often already have risk groups assigned or biosafety levels recommended. Research with such biological agents does not qualify as "higher risk research" requiring NIH approval; indeed, these experiments currently fall within Section III-D of the NIH Guidelines, clearly demonstrating that for decades NIH has determined that the work can be reviewed by the local IBC and does not require NIH approval.
2. Scientists tend to use the words "emerging" and "novel" interchangeably. The definition provided in the Policy for "novel" might more accurately be described as "bioengineered" by the regulated community.
3. We recommend that research involving chimeric agents generated within the same family (for viruses) or the same genus (for bacteria or fungi), may be reviewed by the IBC.
4. We recommend that research involving chimeric agents where the natural sources have risk groups assigned and/or biosafety levels recommended, may be reviewed by the IBC.
f. Section IV-2 (Research That Requires IBC Review and Approval Before Initiation)
i. This section states "For initial submissions of research within the scope of the policy, and not otherwise specified in other sections, review and approval must be obtained from the IBC before initiation."
ii. Since the Policy includes a regulatory catch-all ("not otherwise specified in other sections"), the Policy must include a section that clearly delineates research that is outside the scope of the Policy. Institutions cannot rely on one-off notes to define research that is outside the scope (e.g., "[Note: Experiments involving RG1 wild-type biological agents are not subject to this Policy]"). Without clear delineation, entities will vary widely between unintentional noncompliance and overly requiring IBC review and approval for work that is outside the scope of the policy.
g. Section IV-2: Research involving RG3 or RG4 wild-type biological agents.
i. We have no objection to including RG3 and RG4 biological agents within scope of the Policy, as our institution already requires that work with these agents be approved by the local IBC.
h. Section IV-2: Research involving genetically modified cells, viruses, or organisms, other than plants (e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs).
i. Policy must be well written and clear; this category is a clear example of policy that is not well written. It is misplaced within the tiers of review; contains terms that are either not defined or badly defined; and conflicts with other categories of research within the Policy. Entities will be uncertain how to comply with this category, leading to chilling effects on the research community, additional administrative burden, and unintentional failures to comply with the Policy.
ii. This category is misplaced within the tiers of review. Research with genetically modified cells should be at most within Section IV-3 (delegate review), if not Exempted completely.
1. The NIH Guidelines has included an exemption for recombinant DNA molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in tissue culture at least since the Federal Register Notice in 1994 (Effective June 24, 1994, Published in Federal Register, July 5, 1994 (59 FR 34472)). The NIH Director has therefore determined that such experiments do not present a significant risk to health or the environment. The Policy does not describe how the inclusion of such research in the Policy will increase biosafety and biosecurity. In addition, while a single researcher registering for this work would not be a significant burden, the total number of registrations will constitute a significant collective administrative burden on the IBC and researchers that is not

commensurate with the very low biosafety risk.
2. Genetic modification of cells is of very low biosafety risk (barring some introduction of nucleic acids from certain biological agents, like RG3 or RG4 agents, or that will generate toxins). Such work should be exempt from the Policy.
iii. Genetic modification is defined by the Policy, but in such an expansive way that it is prohibitive to research.
1. As an example: as written, the Policy no longer considers administration of recombinant nucleic acids (e.g., RNA vaccines) in humans to be within scope, compared to the NIH Guidelines, where it is within scope (Section III-C-1). However, the Policy includes "genetic modification" of cells and organisms, which as defined includes introduction of nucleic acid molecules that can be transcribed or translated (e.g., RNA vaccines). The Policy does not describe how it has conducted a risk assessment in which deliberate administration of an RNA vaccine into a human is not within scope, yet transfection of the RNA vaccine into cell culture or administration into an animal is within scope and requires IBC approval.
iv. Organism is not defined by the Policy, which makes this category frustrating to understand and will lead to significant unintentional noncompliance.
1. As written, this category appears to include animals, despite the category of "transgenic organisms at BSL1/ABSL1" listed in Section IV-3.
2. The word organism must be defined by the policy or replaced in this section.
v. Vector is not defined by the Policy, which will lead to significant unintentional noncompliance. Is the intention here to regulate viral vectors (e.g., lentiviral), arthropod disease vectors (e.g., mosquitoes), or something else?
vi. Gene drive modified biological agents is not defined and is a confusing term. Biological agents in the Policy are defined as bacteria, viruses, fungi, or parasites, yet gene drive technology requires Mendelian genetics, such that this would be limited to fungi or parasites. The subsequent use of GDMO in this category suggests that gene drive modified biological agents are different from GDMOs, but this delineation is not clear.
vii. GDMOs are not defined in the Policy.
viii. We recommend that this category be removed from the Policy or extensively re-written, as described below.
1. The definition for Genetic Modification should be re-written to be limited to stable alterations in the genome. Definitions for organism, vector, GDMO and gene drive modified biological agents must be added to the Policy (or removed).
2. Research with genetically modified risk group 3 and 4 biological agents should be approved by the IBC. Research with genetically modified risk group 2 biological agents should be approved by IBC delegate.
3. Research with GMDOs should be approved by the IBC.
4. Review and approval of research with genetically modified cells should be dependent on the modification, some of which may fall within IBC approval, delegate approval, or be completely exempt from the Policy.
i. Section IV-2: Research with primary cells that may be contaminated by adventitious agents.
i. As noted above, the Policy does not define adventitious agents. Therefore, entities will be uncertain how to comply with this regulation and will rapidly be in noncompliance.
ii. If the intention of the Policy is to regulate primary cells that may be contaminated by bloodborne pathogens, there is a significant risk assessment issue: research with samples that may be contaminated requires full IBC review, yet research with known RG2 biological agents requires delegate review.

iii. For clinical samples suspected to contain higher consequence pathogens (Brucella, Herpes B, M. tuberculosis, etc.), the BMBL states that BSL2 practices, containment equipment, and facilities are recommended for routine handing of clinical specimens of human or animal origin. The Policy should harmonize the level of review required for these samples: at most they should require delegate review.
1. We recommend that this section be removed from the Policy.
2. If it must be regulated by the Policy, "adventitious agent" must be clearly defined within the Policy.
3. If it must be regulated by this Policy, we recommend that this work not require IBC or delegate approval as long as the entity is complying with OSHA Bloodborne Pathogens Standard or its equivalent.
4. If it must be regulated by this Policy, we recommend that it should not fall under the category of requiring IBC approval and should at most be in Section IV-3, where delegated review is permitted.
iv. If the intention of the Policy is to regulate primary cells that may be contaminated by any unknown biohazard (for example field samples), that is not clear and needs to be much more clearly defined.
j. Section IV-2: Research with wild type or genetically modified RG2 biological agents for which lower containment is requested, or research with wild type or genetically modified RG3 or RG4 biological agents that NIH has previously approved to be conducted at lower containment.
i. The Policy implies that there will be a workflow of (1) an entity submits an initial request for NIH to lower containment involving wild type or genetically modified RG3 or RG4 biological agents, (2) NIH will make a determination on whether that lower containment is appropriate, (3) NIH will be responsible for publishing approved determinations of appropriate lower containment for these agents, (4) subsequently, research involving these agents may be approved by the IBC alone (without NIH approval).
1. This workflow should be expressly stated in the Policy to minimize confusion. This includes a clear statement that once NIH has made the determination and published it, other entities will not be required to obtain NIH approval. This would be in contrast to the current system, where approvals are provided only to the single PI at the single institution.
2. The method by which NIH will publish these determinations should be described, including the minimum time frame (determinations will be published within 1 month, within 6 months, annually, etc.).
3. The Policy should be clear on how much information will be released together with these determinations. Specifically, whether the information includes security sensitive information or unpublished data.
k. Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): Research involving RG2 wild type biological agents.
i. We have no objection to including RG2 biological agents within scope of the Policy, as our institution already requires that work with these agents be approved by the local IBC.
ii. However, we are very concerned that there is not a thorough list of RG2 biological agents and/or biological agents that are recommended to be worked with at BSL2. Will all agents not listed in the BMBL require review by NIH?
iii. We recommend that the NIH make a detailed, publicly available list of RG1, RG2, RG3, and RG4 biological agents to supplement the BMBL. Appendix B of the NIH Guidelines should serve as the backbone of this document.
1. The inclusion of RG1 organisms is an important part of such a list, since they are outside the scope of the Policy, yet the Policy specifically states that "absence of agent specification in the list of RG2-RG4 does not imply automatic or implicit classification as RG1".
2. If other federal entities (USDA, CDC, etc.) participated in creating a central list that also includes plant or agricultural considerations, that would be greatly appreciated.

iv. If NIH cannot make a detailed publicly available list of RG1, RG2, RG3, and RG4 biological agents to supplement the BMBL, we recommend that the Policy clearly states that the local IBC has the authority to perform the risk assessment and make that determination.
l. Section IV-3: Research conducted with transgenic organisms at BSL-1/ABSL-1.
i. The purchase and transfer of transgenic rodents requiring BL1 containment is exempt in the NIH Guidelines (Appendix C-VII). Further, the generation of certain BL1 transgenic rodents is exempt in the NIH Guidelines (Appendix C-VIII). In 2011, NIH deemed that "… these breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk." (January 19, 2011, Federal Register, January 19, 2011 (76 FR 3150)). As documented in NIH guidance documents, the subsequent use of these BL1 transgenic rodents is also exempt (https://osp.od.nih.gov/wp-content/uploads/2022/11/Animal_Activities_Table.pdf). The same risk assessment should apply today, and the Policy should not require that work with transgenic rodents that can be housed at ABSL1 be approved by the IBC.
ii. As noted previously, there is no definition of organism in the Policy. Therefore, we recommend changing this to animal in this section.
iii. We understand that research with some transgenic animals may not have had the time to demonstrate the same safety track record as transgenic rodents and therefore should continue to require IBC approval before that research is conducted. We would recommend that NIH seriously consider that transgenic fruit flies or zebrafish could be exempted due to their safety track record.
iv. We recommend that this be re-written as: Research conducted with transgenic animals, other than transgenic rodents, fruit flies, and zebrafish that may be housed at minimum BSL-1/ABSL-1/ACL-1.
m. Section IV-3: Research with genetically modified RG1 biological agents.
i. Certain research not requiring NIH-OSP approval and not involving DNA from RG3, RG4, or restricted organisms with specific risk group 1 biological agents is exempt in the NIH Guidelines (Appendices C-II, C-III, C-IV, and C-V), having been determined by the NIH Director to not present a significant risk to health or the environment. The Category here (research with genetically modified RG1 biological agents) icontradicts this determination and would require that work that was previously exempt now requires IBC approval. The Policy has not described why this risk assessment has changed.
ii. We recommend that this category be removed from the Policy.
iii. Additionally, a list of RG1 biological agents is not available. If any part of the Policy references RG1 biological agents, including as work that is outside the scope of the Policy, a list should be developed and published by NIH as part of this Policy, or the local IBC should be granted the authority to designate agents as RG1.
n. Section IV-3: Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes.
i. This category of research is of low biosafety and biosecurity risk. The Policy fails to describe how regulating this research will increase biosafety or biosecurity. This category will set entities up for failure, with no clear benefits to our biosafety programs.
ii. Registering research with plasmids will lead to extensive unintentional noncompliance. Researchers generate plasmids regularly and the requirement to obtain approval for these plasmids from the IBC will be a severe bottleneck.
iii. The Policy fails to describe the extent of what is required to be registered as part of this section. Only

the plasmid backbone? The backbone with every gene the researcher will insert? The backbone with every gene and every mutation of that gene?
iv. The administrative burden for researchers and the IBC will be significant and is not balanced by any increase in biological safety.
v. We recommend that this category be removed from the Policy.
o. Section IV-3: Research with well-characterized cell lines.
i. Registering work with well characterized cell lines will lead to extensive unintentional noncompliance. The administrative burden will be crippling for researchers and IBCs. This category will set entities up for failure, with no clear benefits to our biosafety programs.
ii. The Policy fails to describe the biosafety concern that is being addressed by this category of research.
iii. The Policy does not describe the extent of what is required to be registered. Is it solely that a researcher is performing work with cell lines? Is it every cell line that the researcher will work with? May the entire ATCC catalogue be approved?
iv. We recommend that this category be removed from the Policy.
p. Section IV-3: Research with biological toxin proteins not on the Select Agent list.
i. Under the definition within the Policy, this category includes food allergens, animal allergens, even FBS, since they can cause harm to humans, yet there is no indication that this is intended. The milk that a researcher is using as part of a Western blot falls within the scope of this category.
1. There is a conflict between the wording in this Section (research with biological toxin proteins) and the definition in the Policy for Toxin (a protein or peptide produced …). This conflict makes it difficult to understand what is within the scope of the category.
ii. This category of research must include a clear definition of which toxins are within scope, including an LD50, or entities will be inadvertently noncompliant.
iii. At our institution, work with toxins are already regulated by our Chemical Safety Committee, which provides regulatory oversight of this work. Additional oversight by the IBC will not increase safety and will instead increase regulatory burden.
iv. We recommend that this category be removed from the Policy.
v. If this category is not removed, we recommend that this be re-written as: Research with biological toxin proteins with an LD50 in vertebrates of <100 micrograms per kilograms of body weight.
1. Additionally, a list of toxins currently classified under this category must be provided in the Policy. The list of toxin molecules classified as to LD50 that is currently available from NIH OSP under the NIH Guidelines (Appendix F-1) should serve as the backbone of this list.

3. Continued utility of Risk Groups: 3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).
a. Risk Groups as Hazard Characterizations vs. Site-Specific Risk Assessment
i. Risk Groups remain valuable tools for initial hazard communication and agent characterization, but they should not independently dictate containment or review levels. The final policy must preserve site-specific and experiment-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations. This aligns with Section V-E of the draft policy, which explicitly acknowledges that Risk Groups and Biosafety Levels are related but non-equivalent concepts.
b. Critique of Mandatory IBC Petitions for Emerging, Novel, or Unlisted Agents (Section III-B)
i. The 'IBC Functions' section (fifth bullet) directs the IBC to petition NIH to determine the minimum

biocontainment level for emerging, novel, or zoonotic agents 'for which the RG classification or containment level is not available in the BMBL,' prohibiting IBC approval until authorized by NIH and any other applicable entities.
ii. Terminology Inconsistency: The draft text treats 'RG classification' and 'containment level' as alternative terms residing in the BMBL. However, Section V-E correctly states that RGs and BSLs are non-equivalent. NIH must use these terms consistently across all policy sections.
iii. BMBL Functionality & Misconception: The Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual does not assign Risk Groups; it provides Agent Summary Statements with recommended Biosafety Levels. A regulatory condition referring to an RG classification 'in the BMBL' cannot be fulfilled.
c. Jurisdictional Ambiguity: The phrase 'and any other applicable Federal, State, or local entities' introduces immense ambiguity. NIH must explicitly identify these entities, specify whether approvals are sequential or concurrent, clarify coordination protocols, and establish resolution pathways when determinations conflict.
d. Overbroad Scope & Unintended Petition Backlogs: As written, the petition requirement could be interpreted as applying to non-pathogenic genetically modified constructs or benign RG1 organisms that are not explicitly named in the BMBL. NIH must explicitly clarify that unlisted, non-pathogenic RG1 agents do not require federal petitioning.
e. Reusable Determinations & Response SLAs: Section III-D commits NIH to publishing determinations for lowering RG3/RG4 containment but omits determinations for emerging or novel agents. NIH should publish all containment determinations (agent, modification, approved containment, and rationale) in a searchable public database that other institutions may rely upon as established precedent. Furthermore, NIH must set a target response timeline (e.g., 30 calendar days) rather than relying on the subjective term ”timely.”
f. Definitive Source for Risk Group Assignments
With Risk Group assignments removed from the former Appendix B and absent from the BMBL, NIH must provide an authoritative, version-controlled federal repository or clear objective criteria for assigning Risk Groups to non-recombinant agents. Without standardized federal classifications, institutions will reach conflicting conclusions for the same agent, compromising national oversight consistency.
g. Avoid Rigid Containment Prescriptions (GDMOs and Influenza Research)
Rigid, one-size-fits-all containment rules conflict with performance-based risk assessment. A universal minimum of BSL-2 for Gene Drive Modified Organisms (GDMOs) does not map effectively to specialized containment systems (e.g., Arthropod Containment Level [ACL] guidelines, USDA/NCAR Greenhouse standards, or aquatic facilities). NIH should permit equivalent risk-based containment modalities and issue specialized guidance. Additionally, containment mandates for influenza constructs should specify exact phenotypic traits, host range, and pathogenicity markers rather than sweeping in constructs based on raw genomic segment proportions.

The draft policy treats Risk Groups (RGs) as mandatory containment triggers rather than hazard descriptors, so NIH should explicitly confirm in Section V-E that RGs do not independently dictate BSLs and preserve local risk assessment. The draft also cites RG lists in the BMBL, which do not exist, and lacks scope limits on petitioning, so NIH should correct the BMBL reference and exclude non-pathogenic RG1 agents from mandatory federal petitioning. In addition, the draft makes no commitment to publish determinations for novel or emerging agents, so NIH should publish all containment decisions in a

searchable public database with a 30-day target review timeline. Finally, the draft applies a universal BSL-2 to GDMOs and rigid segment ratios to influenza, so NIH should allow specialized containment (ACL, greenhouse, and aquatic) and calibrate influenza rules to phenotype.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.
a. Refine the definition of a reportable incident and provide clearer thresholds for reporting to support a risk-based, consistent approach across institutions. Clear thresholds improve consistency and allow NIH to focus regulatory oversight on events with true potential public health or community significance.
b. Decouple Regulatory Reporting from Public Website Posting: Requiring institutions to publicly post unredacted investigative reports and meeting minutes for routine or minor incidents creates severe unintended consequences:
i. Publicly posted incident reports inadvertently provide sufficient detail to identify involved personnel.
ii. Publicly linking Principal Investigators, grant numbers, and specific facility locations exposes researchers to harassment, physical threats, and targeted cyber-attacks, particularly in sensitive animal research domains.
iii. Aggregated public postings reveal institutional research security information. Automated AI scraping tools can harvest these public records to map national high-consequence research capabilities, directly conflicting with federal research security directives and Select Agent regulations.
iv. Forcing minor, fully mitigated events into public view suppress internal reporting of near-misses and borderline events out of fear of public backlash or reputational damage.
c. Resolving Undefined Categories & Technical Definitions: To eliminate ambiguity, prevent administrative overload, and protect local reporting culture, NIH must establish precise definitions for the following core terms in Section II:
i. Incident: A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.
i. Release (Loss of Containment or Occupational exposure): Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
ii. Basic First Aid vs. Agent-Specific Medical Treatment: NIH must explicitly align medical treatment with OSHA standards (care beyond basic first aid). NIH must clarify that precautionary, non-specific post-exposure prophylactic (PEP) treatment or routine medical consultations do not constitute agent-specific treatment triggering 24-hour federal reporting.
iii. Potential Exposure: Must be defined as an event occurring in the active presence of a biohazard where primary barriers or PPE were breached, creating a credible exposure pathway. Equipment or PPE failures occurring in the absence of active biohazardous agents are not potential exposures.
iv. Compliance Violation vs. Administrative Non-compliance: Must distinguish administrative non-compliance (e.g., late paperwork, minor log errors) from substantive biosafety non-compliance (e.g., unapproved research initiation or unauthorized containment lowering). Administrative non-compliance and low-risk items must NEVER necessitate a 24-hour reporting timeframe.
v. Minor Spill: Must remove subjective terms like generally and define minor spills.

d. Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries.
i. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

6. Other feedback relevant to this resource: 6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.
a. Provide risk assessment guidance for self-aggregating proteins (Policy Sections II and V-A). The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.
b. Clarify oversight of computational and AI assisted work (Policy Sections II and V-C). Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.
c. Provide a minimum 24-month phased implementation period The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.
d. Pilot the policy and templates: NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.
e. Develop implementation resources: Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.
f. Address the cost of compliance: The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.
g. Allow flexible institutional models: The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and

specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

393. ATCC (American Type Culture Collection)

I am responding: On behalf of an organization

Name: Heather Couch

Name of Organization: ATCC (American Type Culture Collection)

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biological resource centers, culture collections, and repository operations handling biohazardous and genetically modified materials, including microbial strains, cell lines, and nucleic acid preparations used for authentication, production, quality control, and distribution rather than investigator-driven research.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Yes. The draft is written for investigator-driven research protocols and does not address biological resource centers, culture collections, repositories, or the production, quality-control, and distribution activities those organizations perform. “Biomedical research” is tied to the NIH mission but gives no operational test for a mixed-function organization to determine whether a given activity is covered. As a result, routine accessioning, preservation, authentication, standardized characterization, production, storage, and distribution become ambiguous the moment the material is a biohazard or has been genetically modified, even when no new scientific knowledge is being generated.

ATCC recommends that NIH adopt an activity-based scope test: define covered research by the purpose and design of the activity, treating work intended to generate generalizable scientific knowledge as research, while routine repository, production, diagnostic, quality-control, regulatory, commercial-service, storage, and distribution activities conducted under established procedures should not automatically become research solely because of the material’s hazard or modification status. NIH should expressly exclude routine operations conducted under established procedures unless the work is designed to generate new scientific knowledge, and should clarify that activities falling outside the policy’s research scope remain subject to applicable occupational safety, select-agent, transportation, environmental, public-health, quality-system, and institutional biosafety requirements, so excluding an activity from IBC research review does not mean it is unregulated.

NIH should also provide worked examples distinguishing routine repository operations (receipt, accessioning, preservation, authentication, sequencing, quality-control testing, production, and distribution of a deposited strain) from a distinct research project using that material to answer a scientific question, and should clarify when funding relationships (awards, subawards, contracts, collaborations, or service arrangements) trigger applicability in a mixed-function organization.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Review requirements should track the hazard of the resulting material and the proposed activity, not genetic-modification status alone. Relevant criteria include pathogenicity, transmissibility, replication competence, host range, route of exposure, scale, aerosol-generating procedures, environmental persistence, countermeasures, and biological and physical containment. A documented risk-reducing modification (attenuation, replication deficiency, chemical mutagenesis) should make a derivative eligible for the same or a lower review pathway than its wild-type parent, consistent with the draft's own requirement to evaluate how a modification changes risk factors.

ATCC recommends a tiered structure: full IBC review for activities presenting credible, unresolved, or higher-magnitude hazard; delegated review, conducted by the BSO or qualified biosafety staff with defined documentation and conflict-management standards, for activities with established risk profiles or minor amendments; and defined activity-, SOP-, platform-, or facility-based authorizations for routine work conducted within specified material, manipulation, and containment boundaries, with escalation whenever an activity exceeds those boundaries. This same calibration should extend to natural isolates, type strains, taxonomic reclassifications, primary cells, well-characterized cell lines, nucleic acids, inactivated materials, and sequence-derived records, each of which needs clear criteria to prevent inconsistent or unnecessary escalation.

On renewal and monitoring, NIH should clarify that unchanged, lower-risk activities with no significant incidents may use delegated rather than full convened review, and should let institutions rely on existing routine biosafety inspections, facility certification, and quality-system review rather than imposing duplicative IBC-specific inspections.

3. Continued utility of Risk Groups: Risk Group and containment should stay distinct: Risk Group informs the hazard assessment; containment (BSL) should reflect the actual proposed activity. A taxonomic name change shouldn't reset a prior Risk Group determination absent new hazard evidence.

The draft's definition of genetic modification includes stable alterations introduced through passaging, reassortment, and chemical or radiological means. Read with the tiering provisions, this can place an attenuated or otherwise risk-reduced derivative into a higher review category than its wild-type parent, which is inconsistent with the draft's own instruction to evaluate how a modification changes pathogenicity, transmissibility, host range, and other risk factors.

ATCC recommends that NIH keep Risk Group and containment conceptually distinct: Risk Group should inform the hazard assessment, while containment (Biosafety Level) should reflect the proposed activity and the resulting material's actual risk profile, not an automatic function of the parent organism's classification. NIH should specifically clarify the review pathway for attenuated, replication-defective, passage-derived, chemically mutagenized, and vaccine-seed materials, basing the review category on pathogenicity, transmissibility, replication competence, host range, exposure route, scale, and containment rather than genetic-modification status alone. The final policy should avoid categorically excluding all RG1-related work from flexibility; instead it should provide clear low-risk criteria and proportionate delegated review where the evidence supports it.

This same misalignment risk applies to taxonomic reclassification: a name change should not by itself

make a previously evaluated organism administratively "unlisted," so NIH should maintain a living classification resource and carry forward the prior Risk Group assessment after a name change unless new hazard evidence warrants reassessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary adoption will depend on the policy being genuinely usable outside the NIH-funding context it was designed for. Non-funded institutions are more likely to adopt the framework voluntarily if NIH publishes the same decision tools it owes funded institutions: scope and tiering decision trees, standard risk-assessment and delegated-review templates, model IBC policies and redaction standards, and searchable precedent determinations tied to specific materials and activities rather than organism names alone.

Reliance and reduced duplication are strong incentives. NIH should clarify when another federal agency's approval (CDC, FDA, USDA, DoD, Federal Select Agent Program) substitutes for or avoids duplicative federal review, and should permit institutions to use integrated governance and review workflows that satisfy multiple applicable policies, including the July 28, 2026 United States Government Policy for Stopping High-Risk Life Sciences Research, without duplicative committees, risk assessments, records, or annual reviews. A non-funded institution is far more likely to adopt NIH's framework voluntarily if doing so also satisfies its other federal and customer-driven obligations rather than adding a parallel compliance burden.

Finally, NIH could offer recognition or safe-harbor value, such as treating voluntary conformance as evidence of due diligence in federal procurement, grant eligibility, or partnership decisions, and could extend access to the National Biosafety Data and Safety Analysis Center's de-identified learning outputs to voluntarily participating institutions, giving them a direct benefit (shared incident learning and precedent) in exchange for adopting the practices.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The templates should define objective, bright-line thresholds for what constitutes a reportable incident (laboratory-acquired infection, community risk, loss of containment, release, exposure, agent-specific treatment versus basic first aid, equipment failure, inventory or security issues with public-health consequences) so that routine alarms, precautionary consultations, or equipment faults that triggered no credible exposure or release do not automatically require a federal report. The reporting template should distinguish precautionary notification from a confirmed reportable incident, and should allow institutions to supplement, correct, close, or withdraw an initial notice after investigation, with a visible, auditable amendment history rather than treating every initial report as final.

For public posting, ATCC recommends a two-layer approach for both templates: a complete, access-controlled version containing full provenance, evidence, and rationale, and a public-facing version using standardized permitted redactions for confidential commercial information, depositor and customer identities, personally identifiable and occupational-health information, facility configurations and security vulnerabilities, and information that could facilitate misuse. For meeting minutes specifically, the template should allow delegated-review approvals to be reported by neutral protocol identifier, review category, decision, conditions, and date, rather than reproducing the complete confidential record, and should not make public access to meetings the default where proprietary, security-sensitive, or active-

investigation matters will be discussed.

For the National Biosafety Data and Safety Analysis Center, NIH should limit mandatory institutional posting to incidents of confirmed public-health or environmental significance, use de-identified national summaries for lower-risk events, allow delayed publication during active investigations, and provide correction and appeal procedures. A safe harbor for good-faith redaction decisions made under NIH's own standards would reduce institutions' administrative and legal exposure without reducing transparency where it matters.

6. Other feedback relevant to this resource: The six-month effective date is insufficient for institutions to identify newly covered activities, revise policies and charters, recruit and train IBC members, establish delegated review, convert registrations, implement public-facing websites and redaction procedures, build incident workflows, and submit a Biosafety Assurance. ATCC recommends at least an 18-month phased implementation period, with additional time for converting legacy activities, and a documented transition mechanism that lets work appropriately authorized under prior institutional requirements continue while that conversion occurs.

The most valuable resources NIH could provide are: scope and tiering decision trees (including the activity-based test for distinguishing research from routine repository, production, and distribution work); standard risk-assessment, delegated-review, incident-assessment, and Biosafety Assurance templates; model IBC policies, redaction standards, renewal criteria, and post-approval monitoring approaches; training for IBC members, BSOs, investigators, and institutional officials; worked examples specific to repositories, core facilities, contract laboratories, manufacturing support, quality control, and distribution, since the current draft materials are written almost entirely around investigator-led research protocols; and a searchable FAQ and precedent registry with persistent identifiers, current and former taxonomic names, material identifiers, evidence considered, and assigned containment, so determinations can be reused rather than re-litigated at each institution. NIH should also publish an administrative-burden analysis and guidance on allowable implementation costs, and should clarify BSO qualification standards so that demonstrated biosafety knowledge, experience, and training, not degrees or credentials alone, are recognized as sufficient.

Description: ATCC Technical Public Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice NOT-OD-26-112). This document provides detailed recommendations on defining the boundary between covered research and biological-resource-center operations; calibrating oversight to risk; treating emerging, novel, and taxonomically reclassified agents and type strains consistently; aligning Risk Group classification with containment for genetically modified and risk-reduced agents; defining primary cells and well-characterized cell lines; using genomic evidence appropriately; clarifying nucleic acids, inactivated materials, and digital sequence records; protecting confidentiality and security in public transparency mechanisms; defining delegated review, renewal, monitoring, and amendment processes; setting objective incident-reporting thresholds; reducing duplication with other federal oversight; and providing a realistic transition period and implementation tools.

394. Medical College of Wisconsin

I am responding: On behalf of an organization

Name: Nathan Berken

Name of Organization: Medical College of Wisconsin

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): The Medical College of Wisconsin (MCW) appreciates the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. MCW supports NIH's goals of modernizing biosafety oversight, reducing burden for low-risk research, and aligning Institutional Biosafety Committee (IBC) practices with the IRB and IACUC models. The comments below follow the topics identified in the Request for Comment. Within each topic, MCW offers a brief summary of its perspective, followed by specific observations and questions that we hope will help bring greater clarity to the final policy. MCW thanks NIH for considering these comments and would welcome the opportunity to provide further input as the policy and its implementation resources are developed.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Summary: MCW supports a broader, risk-based scope for biosafety oversight. In reviewing Sections II, III-A and III-B, our analysis identified several areas where additional definition or clarification would help institutions apply the policy consistently. These include how the policy's scope relates to clinical settings, how "biohazard" is defined, which institutions are covered by the "any NIH funding" provision, the role of the Biological Safety Officer (BSO) at BSL-2, and the incident reporting and public posting expectations. Several of these provisions may add administrative burden without a corresponding biosafety benefit, and some raise privacy considerations. As MCW reviewed this portion of the rule, our analysis raised questions that could help inform greater clarity within the rule, such as:

- Scope and clinical settings: The scope is defined as "all biomedical research, in lab settings, involving biohazards," while the definition of "Laboratory research" includes clinical settings. MCW would welcome clarification of how clinical settings are intended to be treated, as the current terminology may be read in more than one way.

- Definition of biohazard: The policy refers to "biohazards" but does not define the term on its own. MCW suggests NIH consider revising the definition of "Biological agent" to be neutral, and adding a risk-based definition of "biohazard" or "biohazardous agent."

- Institutions with other NIH funding: The policy applies to NIH-supported research and to non-NIH-funded research at any institution that receives NIH funding. Could NIH clarify whether this includes

institutions that do not receive NIH funding for research involving biohazards but do receive NIH funding for other research?

- Record retention: Retention of IBC records is tied to funding requirements. Would NIH consider allowing IBC record retention to stand on its own, based on the IBC records themselves rather than on the funding associated with a given protocol?

- BSO at BSL-2: A BSO is required only for BSL-3/BSL-4 and GDMO research. Could NIH share the rationale for not requiring a BSO at BSL-2, given that most institutions conduct BSL-2 work, and clarify expectations for how those institutions should designate this function?

- Periodic review of approved research: Section III-B calls for the IBC to "periodically review approved research to ensure compliance." Is this intended to refer to the de novo review of a protocol every three years, or to a post-approval monitoring program similar to that used by IACUCs? How does it relate to the BSO's responsibility to conduct periodic inspections?

- Compliance violations as reportable incidents: Compliance violations (for example, failure to obtain or maintain IBC approval, or failure to obtain NIH approval to lower biocontainment) are grouped with incidents that pose a significant risk to human health, which triggers 24-hour notification and public posting. Because these are compliance matters rather than health-risk events, MCW asks whether NIH would consider placing them in a separate reporting category without the 24-hour timeline or public posting.

- Animal bites and scratches at BSL-1/ABSL-1 and BSL-2/ABSL-2: As written, the policy appears to direct routine animal bites, scratches and similar events to the IBC. MCW notes that these events are typically managed effectively through Environmental Health and Safety, occupational health and animal facility staff, and asks whether NIH would consider allowing those channels to handle them, reserving IBC involvement for events with a clear biosafety nexus.

- Privacy: Public posting of incident reports could unintentionally compromise the privacy of affected staff. What safeguards or redaction expectations does NIH anticipate?

- Occupational health and safety program (OHSP): Section III-A states that an OHSP, if needed, "should be maintained as part of the overall biosafety program." Are there specific OHSP requirements under this policy, or is the intent to rely on existing regulations and institutional programs?

- Delegated reviewer (Section IV-3): Is the individual to whom review and approval may be delegated defined? Can this be the BSO? Must it be an IBC member other than the BSO? Or is this left to the institution to determine?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Summary: MCW supports the tiered approach to oversight and the opportunity it creates to focus committee time on higher-risk research. Our review of Section IV identified places where category definitions overlap or are broad enough that institutions may apply them differently, and where a distinction between basic and clinical research could further improve efficiency. Clearer examples, defined terms and a narrower

federal trigger would help institutions calibrate oversight to risk and reduce the likelihood that low-risk, well-understood work is routed to full committee or to NIH. As MCW reviewed this portion of the rule, our analysis raised questions that could help inform greater clarity within the rule, such as:

- Terminology: MCW supports the tiered review model. Would NIH consider using "Designated Review" in place of "Delegated Review," which would be familiar to the research community from IACUC and IRB practice?

- Authority of the IBC and reviewers: It would be helpful if the policy stated plainly the full scope of IBC authority, including whether the IBC may disapprove research and request modifications to secure approval. Does a delegated or designated reviewer hold the same authority, or must certain determinations (such as disapproval) be referred to the full committee?

- Clinical research under Section IV-3: As written, Section IV-3 appears to treat clinical and basic research the same way, which would appear to preclude delegated review of clinical studies involving widely used therapeutics, such as CAR-T and other genetically modified, long-lived cell products that have already undergone substantial biosafety evaluation and have been used to treat tens of thousands of patients. MCW suggests NIH consider allowing delegated review for clinical studies, or at a minimum a carve-out for studies involving investigational products that are substantially similar to currently approved products. This could improve throughput and flexibility and support more timely access to new therapies.

- Section IV-1 trigger for NIH approval: Requiring NIH approval whenever an emerging, novel or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents that are routinely handled at BSL-1 and BSL-2 (for example, organisms identified in environmental screens). MCW suggests NIH consider defining the trigger narrowly, permitting qualified IBCs to make interim or final determinations for well-characterized agents, and reserving NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

- Genetically modified materials under Section IV-2: This category is broad and could encompass many standard, low-risk experiments. Could NIH clarify whether it includes transgenic animal tissue, HEK cells, plasmids administered to cells, or cells already modified by a vendor?

- Primary cells under Section IV-2: "Research with primary cells that may be contaminated by adventitious agents" appears to relate to bloodborne pathogen risks that many institutions review outside of full-committee meetings. Could NIH clarify whether this includes all human cells, or any cell permissive to a human pathogen?

- Overlap between Sections IV-2 and IV-3: Genetically modified cells, viruses and organisms appear in IV-2 (full IBC review), while subsets of the same materials appear in IV-3 (delegated review). More precise delineation between the two would help avoid inconsistent application.

- "Well-characterized cell lines": Will NIH provide examples, or is this determination left to the

institution?

- Plasmids and viral vectors: Research with "plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes" is placed in IV-3. MCW suggests NIH consider retaining replication-incompetent, non-integrating viral vectors in IV-3 while moving plasmids expressing reporter or low-risk transgenes to an exempt category. Will NIH provide examples of "low-risk transgenes"?

- Transgenic organisms at BSL-1/ABSL-1: Could NIH clarify what is meant by "transgenic organisms," including whether this covers transgenic rodents, Drosophila and USDA-regulated species? If so, does it extend to breeding or purchase and transfer of transgenic rodents, activities that were previously exempt?

- Genetically modified RG1 agents: Does this category include E. coli and S. cerevisiae used for plasmid propagation or protein expression?

3. Continued utility of Risk Groups: Summary: MCW finds the Risk Group information in the current NIH Guidelines valuable when assessing biological agent risk, and it works well alongside the biosafety level guidance in the BMBL. We encourage NIH to retain RGs as a baseline for risk assessment. Because the draft policy relies on RG classifications in several places, timely access to the supplemental RG materials NIH has described will be important for institutions preparing to implement the policy. As MCW reviewed this portion of the rule, our analysis raised a question that could help inform greater clarity within the rule:

- Timeline for RG materials: The policy notes that NIH intends to provide supplemental materials on RG classifications. Does NIH have an approximate timeline for making these available?

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): n/a

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Summary: MCW supports transparency and consistent documentation of IBC activity. However, our review suggests that required templates, accelerated approval timelines and broad public posting of incident reports could create significant operational burden, particularly for institutions using electronic protocol systems, and could unintentionally discourage full reporting by investigators. MCW offers alternatives that we believe would meet NIH's transparency and oversight goals while allowing institutions flexibility in how they document and communicate this information. As MCW reviewed this portion of the rule, our analysis raised questions and suggestions that could help inform greater clarity within the rule, such as:

- Meeting minutes template: Many institutions use electronic systems, and a required template would likely necessitate substantial programming changes. MCW suggests NIH consider specifying the elements that minutes must include and allowing institutions to develop their own format. This would also bear on the realism of the proposed six-month implementation period.

- Timing of minutes approval: Requiring approval no later than the next convened meeting may be difficult in practice. Many IBCs allow members to request changes before voting, which can mean

minutes are approved at the following meeting. Would NIH consider a more flexible timeframe?

- Public posting and PI and grant information: Including the PI name and grant number is appropriate for reports submitted to NIH, but MCW suggests that this information be redacted when reports are publicly posted. More broadly, MCW believes public posting of all incident reports may be unnecessary. As an alternative, institutions could describe their incident reporting procedures in the Biosafety Assurance, submit the appropriate incidents to NIH, and maintain internal records of all others.

- 24-hour reporting: Immediate reporting within 24 hours may not be necessary in most cases. MCW suggests NIH consider allowing institutions to address the situation first and then file a report that includes the resolution.

6. Other feedback relevant to this resource: Summary: MCW anticipates that implementation will require substantial effort, including converting existing protocols, updating electronic systems and obtaining an approved Biosafety Assurance before research can proceed. Our principal requests are for a longer implementation period, an opportunity to review and comment on the Assurance template, and clarification of several terms (externally administered IBC, non-affiliated member, minor amendment) that will directly affect how institutions structure their programs. We also share concerns about the scope of public posting, and we suggest a model based on the Animal Welfare Assurance that we believe would meet NIH's goals with less burden. As MCW reviewed this portion of the rule, our analysis raised questions that could help inform greater clarity within the rule, such as:

- Implementation timeline: A six-month implementation period appears insufficient given the hundreds of protocols to be converted and the time needed to obtain an approved Assurance. MCW recommends at least 18 months, although three years may be more realistic given the approval period and scope of changes.

- Biosafety Assurance template: The draft refers to a "Biosafety Assurance" and its general content. MCW would appreciate a template and an opportunity to comment on it. Will it be structured similarly to an Animal Welfare Assurance, and will review be comparable? What is meant by "Other pertinent information requested by NIH"?

- Public posting of information: MCW is comfortable providing the requested information in an Assurance. We have concerns, however, about publicly posting some of it on a website, as this is not required for IACUCs. MCW's procedures are available on an intranet for the benefit of investigators and staff. Incident reports that are not required to be submitted to NIH should not need to be included, and we are concerned that posting incident reports in general may create a punitive atmosphere that could interfere with full reporting by investigators. Describing the institution's incident reporting procedure in the Assurance would, in our view, give NIH appropriate assurance that the procedure is in place.

- Externally administered IBC and multiple sites: Could NIH clarify the term "externally administered IBC" and whether each site must have its own IBC of record and its own Biosafety Assurance? MCW suggests NIH consider allowing a single local IBC to serve multiple local locations under one Assurance, provided the covered components are clearly stated. This approach is similar to how Animal Welfare Assurances are handled, would not extend to commercial IBCs, and would meaningfully reduce administrative

burden for local IBCs.

- Non-affiliated members: Could NIH provide a definition of "non-affiliated" member? MCW suggests using the same definition that applies to IACUCs.

- Minor amendments: Could NIH define "minor" amendment, or confirm that institutions may define it by policy and state that definition in their Biosafety Assurance?

395. Donald H. Bouyer

I am responding: On behalf of myself

Name: Donald H. Bouyer

Name of Organization: UTMB Galveston

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious disease

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Biosafety-comments-_DHB.pdf

Description: Extended comments to revised NIH Biosafety policy

October 19, 2026

RE: Comments for the Draft NIH Biosafety Policy for Research Involving Biohazards (Request for Comment – NOT-OD-26-112, dated August 19, 2026)

To whom it may concern,

I am an associate professor that has been teaching and conducting research in infectious and vector borne diseases for the past 28+ years. Before then, the focus of my Ph. D. dissertation research was pathogenic bacteriology. During my career I have published multiple articles on vector-borne diseases and have presented my research and national and international meetings. I have also worked closely with the regulatory and biosafety groups at my institution, so I have some experience with the current and past regulations. My comments regarding the Draft NIH Biosafety Policy for Research Involving Biohazards (the Policy) (NOT-OD-26-112, dated August 19, 2026) are below.
In general, I support the replacement of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). However, I have concerns about the Policy, including the scope, definitions, and tiers of oversight, which are described further below.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.
   a. Increased Administrative Burden: The draft policy requires Risk Group assignments for non-recombinant agents, creating additional administrative workload for institutions.
   b. The proposed Policy uses words/terms but does not define them; some of these did not have definitions in the *NIH Guidelines*, and therefore this is a good opportunity to define these listed below:
      i. Organism
      ii. Transgenic
      iii. Adventitious agent
      iv. Virus as a "living organism"

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).
   a. **General Definitions: *Toxin***
      i. The definition of toxin is poor. Clearly state that "living organism" does not include viruses.
      ii. Alternatively, adopt a clearer definition. For example, ISO35001 uses "substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants. This includes substances and

materials, natural or as a result of biotechnology, that may contain toxins, any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance."

b. **Section IV-1 (Research that Requires NIH and IBC Approval Before Initiation):** ***Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL.***
   i. For researchers who identify new biological agents, there is no path to work with these agents. Once identified as an "emerging agent" with no risk group or biosafety level recommended in the BMBL, the research must be approved by NIH. However, without the ability to work on the agent, the researcher cannot generate the data required for NIH to conduct the risk assessment.
      1. **I recommend** that an initial characterization be allowed with the results to be shared with NIH to determine the appropriate Risk Group level.
   ii. Upon the Implementation Date of this Policy, what is the expectation for research with the many agents (especially bacteria and fungi) that are not listed in the BMBL, and are typically handled at BSL1 or BSL2?
      1. Are researchers expected to have obtained approved from the NIH by the Implementation Date? Does NIH OSP have the personnel to review and approve the requests that they will be inundated with?

c. **Section IV-2 (Research That Requires IBC Review and Approval Before Initiation):** ***Research involving RG3 or RG4 wild-type biological agents.***
   i. No comments on this section.

d. **Section IV-2:** ***Research with primary cells that may be contaminated by adventitious agents.***
   i. As noted above, the Policy does not define adventitious agents. Therefore, entities will be uncertain how to comply with this regulation.
   ii. If the intention of the Policy is to regulate primary cells that may be contaminated by bloodborne pathogens:
      1. **We recommend that:** This should not be regulated by this Policy as long as the entity is complying with OSHA Bloodborne Pathogens Standard or its equivalent.
      2. **We recommend that:** If it must be regulated by this Policy, it should not fall under the category of requiring IBC approval and should at most be in Section IV-3, where delegated review is permitted.
   iii. If the intention of the Policy is to regulate primary cells that may be contaminated by any unknown biohazard (including clinical or field samples):
      1. The recommendation is that the sample undergoes genetic testing and analysis initially or is characterized at high or maximum biocontainment.

e. **Section IV-2:** ***Research with wild type or genetically modified RG2 biological agents for which lower containment is requested, or research with wild type or genetically modified RG3 or RG4 biological agents that NIH has previously approved to be conducted at lower containment.***
   i. The Policy implies that there will be a workflow of (1) an entity submits an initial request for NIH to lower containment involving wild type or genetically modified RG3 or RG4 biological agents, (2) NIH will make a determination on whether that lower containment is

appropriate, (3) NIH will be responsible for publishing approved determinations of appropriate lower containment for these agents, (4) subsequently, research involving these agents may be approved by the IBC alone (without NIH approval).

1. This workflow should be expressly stated in the Policy to minimize confusion. This includes a clear statement that once NIH has made the determination and published it, other entities will not be required to obtain NIH approval.
2. The method by which NIH will publish these determinations should be described, including the minimum time frame (e.g., determinations will be published within 3 months).
3. The Policy should be clear on how much information will be released with these determinations (will it include information that will make sensitive information readily available to foreign adversaries?)

f. **Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): *Research conducted with transgenic organisms at BSL-1/ABSL-1.***

i. The purchase and transfer of transgenic rodents requiring BL1 containment is exempt (Appendix C-VII). Further, the generation of BL1 transgenic rodents (Appendix C-VIII) is exempt in the NIH Guidelines. In 2011, NIH deemed that "… these breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk." (January 19, 2011, Federal Register, January 19, 2011 (76 FR 3150)). As documented in NIH guidance documents, the subsequent use of these BL1 transgenic rodents is also exempt (https://osp.od.nih.gov/wp-content/uploads/2022/11/Animal_Activities_Table.pdf). The same risk assessment should apply today, and the Policy should not require that work with transgenic rodents that can be housed at ABSL1 be approved by the IBC.

ii. As noted previously, there is no definition of *organism* in the Policy. Therefore, we recommend changing this to *animal* in this section.

iii. We understand that research with other transgenic animals has not had the time to demonstrate the same safety track record as transgenic rodents and therefore should continue to require IBC approval before that research is conducted.

iv. **We recommend that this be re-written** as: Research conducted with transgenic animals at BSL-1/ABSL-1, other than transgenic rodents.

g. **Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): *Research with genetically modified RG1 biological agents.***

i. Certain research (not requiring NIH-OSP approval and not involving DNA from RG3, RG4, or restricted organisms) with specific risk group 1 biological agents is exempt in the Guidelines (Appendices C-II, C-III, C-IV, and C-V), having been determined by the NIH Director to not present a significant risk to health or the environment. The Category here (research with genetically modified RG1 biological agents) is in contradiction to this

determination and would require that work that was previously exempt now require IBC approval.

ii. **We recommend that this category be re-written as:** Research with RG1 biological agents is exempt as stated under the current policy.

h. **Several sections, including Section IV-2: *Research involving genetically modified cells, viruses, or organisms, other than plants (e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs)* and Section IV-3: *Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes***

i. An exemption for recombinant DNA molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in tissue culture has existed at least since the Federal Register Notice in 1995 (Effective June 24, 1994, Published in Federal Register, July 5, 1994 (59 FR 34472)). The NIH Director has therefore determined that such experiments do not present a significant risk to health or the environment. While a single researcher registering for this work would not be a significant burden, the total number of registrations will constitute a significant collective administrative burden on the IBC and researchers that is not commensurate with the very low biosafety risk.

ii. We recommend that an exemption be added.

i. **Section IV-3: *Research with biological toxin proteins not on the Select Agent list.***

i. The policy needs to be written clearly and concisely, which this category does not accomplish. As written, this would include food allergens, since they cause harm to humans, yet there is no indication that this is intended.

ii. **We recommend that this be re-written as:** Research with biological toxin proteins with an LD_{50} in vertebrates of <100 micrograms per kilograms of body weight.

iii. Additionally, a list of toxins currently classified under this category should be provided in the Policy.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

a. Risk Group assignments have been removed from the NIH Guidelines and are not comprehensively provided in the BMBL. NIH should provide a definitive source or clear criteria for assigning Risk Groups to non-recombinant agents. Without standardized Risk Group classifications, institutions may reach different conclusions for the same agent, reducing consistency across the research community.

b. Please provide the biosafety rationale and supporting evidence that prompted the inclusion of additional oversight requirements for research involving insect cell lines, non-human/NHP cell lines, and pathogens that are not capable of causing disease in humans, including immunocompromised individuals. Clarification of the specific risks, incident history, or emerging concerns that necessitate these requirements would help the research community

understand the basis for the policy change and assess whether the proposed oversight is proportionate to the actual biosafety risk posed by these systems.

c.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
   a. Additional clarification is especially in consideration of collaborations and/or contracts between non-NIH funded and funded institutions.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.
   a. The proposed definition of an incident appears overly inclusive and may capture events with minimal biosafety significance. A broad incident definition could result in unnecessary reporting requirements, diverting resources from investigating and addressing more consequential biosafety events.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.
   a. Refine the definition of a reportable incident and provide clearer thresholds for reporting to support a risk-based, consistent approach across institutions.

7. Other Comments
   a. The responsibilities of the institution (Section III-A) includes the following text (emphasis added) regarding records retention:
      The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states "the recipient and subrecipient must retain all Federal award records for **three years from the date of submission of their final financial report**."
      i. The Policy is assuming that all IBC records are from projects that are NIH funded. The Policy has failed to consider projects that are not NIH funded and therefore will never submit a final financial report. As written, such IBC records may never be disposed of, which is either an oversight or egregious regulatory overreach. **This language needs to be changed.**
      ii. We recommend the following language:

      The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states "the recipient and subrecipient must retain all Federal award records for three years from the date of submission of their final financial report." In the case of IBC records unrelated to Federal awards or where a final financial report is not submitted, it is unclear if documentation must be maintained for 1 year after IBC approval expires. This point need clarification.

8. Research with primary cells that may be contaminated by adventitious agents.
   a. Provide a definition of adventitious agents.
   b. Provide rationale on why primary cells require full IBC review, when wild-type (RG2/BSL2) agents can be reviewed through delegate review. The bulk of adventitious agents are categorized as risk group 2/BSL2 agents when isolated, cultured or purified, by definition this would imply that these agents can be reviewed and approved by delegate review.
   c. For known clinical samples of higher risk group agents (Brucella, Herpes B, Mtb) the BMBL recommends BSL-2 practices, containment equipment, and facilities are recommended for routine handling of clinical specimens of human or animal origin. Why can't delegate review be assigned to these types of samples, with caveat that if samples are positively identified and research will continue, then full IBC review will be required?
   d. Should this bullet be changed to highlight unscreened field or human samples from regions of endemic infections with RG3 and RG4 biological agents?

Reasons to remove from the scope of the Policy

- The work does not pose an appreciable risk to human health or to the environment.
- While registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk.
- Personnel who do not have access to biohazards, nor the ability to gain possession of biohazards, should not subject to the Policy. This is egregious regulatory overreach. As written, the individuals to whom this regulation will apply is broad and vague, which will lead to entities wasting time and effort to identify individuals, overtraining these individuals, and likely still being unable to fully comply with this poorly-written and obviously overreaching regulation. We strongly object to this requirement which will add significant burden to entity's without providing increased safety or security of biohazards.
    - What benefit is there in training an individual who performs administrative functions but does not have access to biohazards? How will training these individuals increase the safety or security of biohazards? This is a waste of resources with no clear benefit.
- Second, will entities be required to retroactively go back and add this information to their current inventory written records? How do the regulators expect this to be accomplished?
- This addition to the regulation will set entities up for failure, with no clear benefits to our biosafety programs.
- The Summary provided in the Policy does not provide an outlined justification for any of the following language changes to xxx. Thus, it is unclear why these changes are being proposed, how they will enhance the protection of human, animal, and plant health and safety, or how it will reduce the likelihood of the accidental or intentional release of a biohazard.

Issues to identify

- The definition is poorly written; regulatory language should be stated in clear, plain language. Such detailed examples should not be used in the regulatory language; if they are required, the original regulatory language is not sufficient and should be revised.
- Regulatory language should clearly and succinctly state a performance-based standard, which this definition fails to accomplish.
- Entities will be uncertain how to comply with this regulation, leading to chilling effects on the research community, additional administrative burden, and unintentional failures to comply.
- We recommend the following definition, based on xxx:
- The proposed definition removes the entity's ability to perform internal risk assessments to determine risk, thereby making all incidents involving biohazards reportable regardless of actual risk of escape and/or occupational exposure. The regulation must allow for the entity to perform risk assessments; it is important to recognize a risk assessment encompasses the whole picture of the event, not a single data point as these definitions imply. Risk assessments for events that may have resulted in an escape or potential occupational exposure are conducted within minutes to hours of potential exposure(s) and often incorporate a whole team of SMEs (biosafety, medical professionals, scientists, engineers) depending on the event to evaluate if the event resulted in escape of pathogen and/or if there was risk of occupational exposures.
- The additional reporting requirements will not enhance the protection of human, animal, or plant health and safety, reduce the likelihood of accidental or intentional release of a biohazard, or increase the probability that a release will be prevented from occurring.
- This change in definition will result in considerable administrative burden for entities with no real change in outcome or reduction in risk.
- Escape of a biohazard outside of primary containment should not require reporting unless a risk assessment has determined that the event resulted in a biohazard escaping beyond the defined biocontainment boundary (following the same definition in the FSAP HVAC policy statements) and/or causing an occupational exposure.

Good feedback

- This is a well written definition. Clear, concise, and with plain meaning. We support adding this definition to the regulations.

As stated previously, I support the replacement of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) as many of my colleagues do. However, there are several areas of ambiguity in the proposed Policy that could lead to confusion and an unintended massive increase in the burden placed on IBC and researchers which will have the chilling effect of hindering research progress. I don't believe that is the goal of this new Policy.

Thank you for your consideration.

Department of Pathology • 301 University Blvd. • Galveston, Texas 77555-0609
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Sincerely,

[redacted]

Donald H. Bouyer, Ph. D.
Director, UTMB BSL3 Research Core
Associate Professor, Department of Pathology
The University of Texas Medical Branch at Galveston
301 University Blvd.
Galveston, TX 77555-0609

396. Federation of American Societies for Experimental Biology

I am responding: On behalf of an organization

Name: Galen Cobb

Name of Organization: Federation of American Societies for Experimental Biology

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Science Policy Analyst

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biological and Biomedical Research - all domains

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: FASEB, a federation of 21 member societies representing more than 100,000 biological and biomedical researchers, thanks NIH for taking on a need the research community has long recognized. The current NIH Guidelines were built around recombinant DNA, while the biological systems and hazards investigators work with today extend well beyond that frame. FASEB appreciates NIH's effort to modernize biosafety oversight and supports the development of a clearly defined, risk-based scope. A single framework addressing biohazards broadly is more coherent than a system in which similar risks may be treated differently based on whether a nucleic acid modification is involved.

FASEB nevertheless asks NIH to further refine the operative scope language before finalization. The threshold phrase "known or potential risk to human health" (Section II) is not sufficiently defined to support consistent application, and individual investigators, particularly trainees and early-career researchers establishing new laboratories, will depend on their local IBC to interpret it. Without additional guidance or illustrative examples, comparable protocols may be scoped differently across institutions, creating administrative burden that is not necessarily related to differences in actual risk. FASEB recommends that NIH supplement the final Policy with a non-exhaustive set of worked examples that would help investigators and IBCs apply the scope consistently.

FASEB also asks NIH to establish a defined transition period following the Policy's effective date. Investigators with active, multi-year awards that were initiated under the current framework should not be required to interrupt ongoing research or undertake retroactive registration without adequate time to assess and implement the new requirements. Full discussion, including specific examples, is provided in the attached letter.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): FASEB supports the introduction of delegated review (Section IV-3) as a meaningful mechanism for calibrating oversight to actual risk, and we appreciate that this pathway is not available under the current NIH Guidelines. For

individual investigators, however, the value of delegated review will depend on whether it provides a materially faster pathway than full-committee review. FASEB recommends that NIH establish an expectation for timely delegated determinations or require institutions to report delegated-review turnaround times so that the effectiveness of this new pathway can be assessed.

FASEB also asks NIH to clarify how amendments limited to a previously approved vector platform, such as testing a new transgene or therapeutic target within an already-characterized AAV or adenoviral system in preclinical models, should be reviewed. Without clarification, routine iterative testing could trigger disproportionate re-review relative to the risk involved. FASEB recommends that such payload-only changes be made explicitly eligible for delegated review consistent with existing categories under Section IV-3. Further discussion is provided in the attached letter.

FASEB is also concerned about the requirement that IBC approval expire after three years and be followed by a full de novo registration and review (Section III-B), regardless of whether the approved research has changed. For investigators working under longer award cycles or training grants, this could create recurring administrative requirements that are disconnected from changes in the underlying risk. FASEB recommends that NIH establish an abbreviated renewal pathway for protocols with no material changes, reserving full de novo review for research that has meaningfully changed in scope, agent, or risk profile.

FASEB recognizes the value of the transparency and accountability measures embedded in this structure. Our concern is that the administrative burden associated with implementing those measures should remain proportionate and should fall as lightly as possible on the investigators conducting the research.

3. Continued utility of Risk Groups: FASEB supports retaining Risk Groups (RGs) as the baseline framework for risk assessment. RGs are the framework most researchers encounter in biosafety training and in the BMBL's agent summary statements and related scientific literature. Replacing or subordinating RGs to BSL-based assessment alone would require the research community to adopt a different primary framework without a clear corresponding safety benefit.

FASEB asks NIH to strengthen guidance for the area the draft Policy identifies as particularly challenging: genetically modified, chimeric, and synthetic biology constructs for which no single parent RG readily captures the characteristics of the resulting system (Sections V-B and V-C). These cases require investigators to synthesize information about source agents, sequence function, biological context, and experimental use, yet many investigators will not have formal training in conducting this level of risk analysis. Worked examples would improve both the consistency of risk assessment and the efficiency of interactions between investigators and IBCs.

FASEB also asks NIH to ensure that the process for NIH-level risk determinations, required when an agent’s classification or containment level is not yet available in the BMBL, proceeds on a clear and predictable timeline, with provision for expedited handling when research responds to an emerging public health threat, such as a shift in hantavirus transmission patterns. Full discussion is provided in the attached letter.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): FASEB supports the creation of the National Biosafety Data and Safety Analysis Center (NBDSAC) and its explicit firewall against using voluntarily submitted near-miss data for enforcement or funding decisions. This is the kind of non-punitive reporting culture that meaningfully improves safety, and FASEB encourages NIH to promote it actively to investigators, in addition to institutions.

FASEB notes, however, one practical difficulty with the protection as drafted. It applies only if the incident did not result in an environmental release or a laboratory-acquired infection, but an institution deciding on whether to submit a near-miss report generally cannot know at that point whether either outcome will later materialize. That uncertainty could lead institutions and investigators to hesitate or to forgo reporting, which is the opposite of what the mechanism is meant to achieve. FASEB asks NIH to clarify how and when this condition will be assessed, and to consider whether the protection can attach to good-faith reports based on what was known at the time of submission.

FASEB raises a significant concern about the incident-reporting requirements as drafted. The required template mandates disclosure of the responsible PI's name in public, non-redactable incident reports, while other individuals involved are identified only by role or title (Appendix B; Section III-A). For an individual investigator, particularly an early-career researcher, this creates a permanent public association between the investigator and a reported incident regardless of the investigator's degree of involvement, fault, or the severity of the event. FASEB is concerned that this asymmetry could discourage the proactive reporting that the Policy is intended to promote. Further, the forms also requires public reporting of the grant number. While we understand the need to include this information for incident tracking, grant numbers allow access to PI names in the public-facing NIH databases and would therefore create the same challenges. NIH should reconsider whether public identification of the PI by name is necessary to achieve its transparency objectives, as distinct from the information NIH requires for internal oversight. FASEB welcomes further dialogue on approaches that preserve accountability without creating a disincentive to report.

On voluntary compliance for non-NIH-funded research, FASEB defers primarily to institutional and research-administration stakeholders that are better positioned to address adoption incentives. We note, however, that broader voluntary adoption will depend in part on whether the framework is viewed as practicable and proportionate to the safety benefit it provides. Further discussion is included in the attached letter.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: FASEB appreciates NIH's release of draft templates alongside the Policy and offers the following practical feedback from the investigator's perspective.

The draft IBC meeting minutes template effectively requires a public-facing, plain-language project description and risk assessment narrative for each registration, work that will often originate with the PI. FASEB recommends that NIH develop PI-facing guidance and model language, in addition to IBC-facing instructions, so investigators understand the expected level of detail and are not required to infer how technical information should be translated for a public audience.

FASEB also asks NIH to clarify the redaction standard. Both templates instruct institutions to redact private or proprietary information "judiciously" without further definition. This creates risks in both directions. Insufficient guidance could result in disclosure of technically sensitive construct or protocol details in permanent public records, while overly broad redaction could undermine the Policy's transparency objectives. FASEB recommends that NIH establish concrete redaction criteria, potentially in coordination with biosecurity expertise where dual-use considerations are implicated, rather than leaving this judgment entirely to individual institutions.

Lastly, FASEB would like to raise a concern over the inclusion of agent inventories and security issues (Section III-B, for BSL-3/ABSL-3 and BSL-4/ABSL-4 work) in publicly posted incident reports. Together, these postings could reveal which agents are held at which institutions and when controls failed, which may expose institutions and investigators to undue media exposure and reputation harm for what are often routine incidents. It could also lead to additional security concerns and increase security management requirements. FASEB asks NIH to consider whether incidents involving inventory or security issues warrant distinct handling for public posting.

6. Other feedback relevant to this resource: N/A

Description: The attached letter is FASEB’s complete response, expanding on the comments above with additional detail, examples, and recommendations, including on tiered oversight, risk determination for novel and emerging systems, incident reporting, implementation resources, and coordination with the U.S. Government Policy for Stopping High-Risk Life Sciences Research. Thank you for considering these comments.

397. Biosafety Administrators Association

I am responding: On behalf of an organization

Name: William Greer

Name of Organization: Biosafety Administrators Association

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: BSAA Coordinator and Meetings Facilitator

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosafety Research Compliance

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk

and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.
Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.
Clinical activities and oversight endpoints
Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.
Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.
Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.
Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.
Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of

corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.
Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language. The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.
As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.
Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.
Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.
Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.
NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review
Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.
Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.
Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.
Proposed designated member review procedure
Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.
If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.
Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

3. Continued utility of Risk Groups: Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.
Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.
Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.
Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.
Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.
Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.
Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

6. Other feedback relevant to this resource: Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.
Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.
Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.
Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders,

including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

Uploaded File: Community_Comments_NIH_Biohazards_Policy.docx

Description: Biosafety Administrator's Association Comments

Community Comments on the Draft NIH Biosafety Policy

Recommendations to the National Institutes of Health Office of Science Policy

We support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving

Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

Policy source

Draft NIH Biosafety Policy for Research Involving Biohazards, NIH Notice NOT-OD-26-112, released August 19, 2026. Section references throughout refer to this draft.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

398. Róża Przanowska

I am responding: On behalf of myself

Name: Róża Przanowska

Name of Organization: Loyola University Chicago

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cancer biology, RNA biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: "The introduction into cells, organisms, or viruses of nucleic acid molecules that can be transcribed or translated" is a s scientifically imprecise and overbroad. definition since such nucleic acid molecules do not stay in cells long-term. Most such molecules, including mRNA, siRNA, and antisense synthetic oligonucleotides (ASOs), are degraded within hours to days and do not persist or replicate in the host. Treating all of them as a biohazard category conflates transient expression with heritable genetic modification or replication-competent agents, which carry very different risks. This reclassification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research, recombinant vaccine technologies, and new therapeutics development, with potentially devastating public health outcomes.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

399. Lynne

I am responding: On behalf of myself

Name: Lynne

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: These comments reflect my own personal opinion and not necessarily that of my employer. I have serious concerns about publishing the names of the IBC members, especially the Local Non-affiliated Member. The potential for their harassment is high. There needs to be a balance between transparency and privacy. I have served on several IACUC's and IBC's over the years. I would no longer server if my name were made public. There is no clear rationale for making public the names of committee members.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: At a minimum, the Local Non-affiliated Members names should be redacted due to the potential for harassment. There needs to be a balance between transparency and privacy.

6. Other feedback relevant to this resource: There needs to be a clear rationale for the need to publicly name IBC members.

400. AAMC

I am responding: On behalf of an organization

Name:

Name of Organization: AAMC

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Association

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The AAMC appreciates the community outreach that NIH has engaged in over the past year as part of the efforts to modernize the NIH Guidelines and strengthen biosafety oversight. We strongly support the development of a biosafety policy which is reflective of the significant progress in science and can effectively address any evolving challenges in conducting work with biohazards and other agents.
In discussions about the draft biosafety policy with AAMC member institutions, we heard often that the academic medical community has had difficulty in providing a comprehensive response to NIH prior to the release of the implementation guidance for the recently issued United States Government Policy for Stopping High-Risk Life Sciences Research. Institutions largely manage their biosafety and potential dangerous gain-of-function (DGOF) projects through overlapping processes and specialized staff. To address these concerns, we recommend that the NIH Office of Science Policy open a public comment opportunity for a minimum of 60 days after the release of the DGOF implementation guidance to allow for further feedback on the biosafety policy, including potential conflicts or additional regulatory burden that would arise in the implementation of the two policies. AAMC remains concerned about the breadth of the DGOF policy, which could dramatically impede the research timeline while an institution reviews all proposed applications for potential DGOF through a new administrative process.

The AAMC urges that as NIH develops the biosafety policy, the agency prioritize harmonization not only with other NIH policies but with other federal research agencies. In particular, many NIH grantees are also conducting research with plant pathogens and are subject to requirements from the U.S. Department of Agriculture (USDA). The NIH and USDA should ensure a coordinated approach to addressing biosafety issues through policies and regulations.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Many institutions already review all research on their campus that falls under the current NIH Guidelines, and some with an even broader scope. However, while many

institutions voluntarily review this research, we do not believe that there is statutory authority for the agency to require that this policy be applied to non-NIH funded research that is conducted at an institution that receives any NIH funding. We urge NIH to limit this policy's application to NIH-funded research to avoid the situation in which this policy has a fundamentally different scope and reach than any similar policy from NIH or other science funding agencies.

Generally, many institutions appreciate that the draft policy is adaptable and reflects the evolving nature of science. However, the broadened scope of the policy combined with a lack of details about its application, adds a substantial amount of low-risk research to the review and oversight process without guidance on which, if any, projects should be exempt from this policy. The policy as currently written could require investigators to register, for example, every plasmid, gene target, and well-characterized cell line, which would be enormously burdensome and divert resources from thorough evaluation of high-risk research. Importantly, this outcome would not align with the NIH's goal of "removing red tape for low-risk research." We propose that the policy identify specific categories of low-risk research or protocol amendments which are not subject to IBC and/or NIH review.

The draft policy is not clear on how delegated review might relieve some of the burden added by the new requirements. We recommend that any oversight required for routine activities, such as the use of low-risk transgenes in cell culture, should be minimal, requiring only that the institution records that this general category of work is occurring and ensures that the appropriate training, facilities, containment, and safety practices are in place.

In conversations with AAMC member institutions, we heard consistent support for the continued use of Risk Group classifications as a baseline for risk assessment, with several comments that the use of these groups is critical and allows for more flexibility based on the research due to its focus on the properties of the agent in question. Biosafety levels were identified as being an important part of a comprehensive risk assessment and determination of the containment levels needed, depending on any changes to the risk level from the specific research being done.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft policy proposes a six-month implementation timeframe, which would be challenging for institutions. The AAMC recommends that NIH adopt a one-year implementation time frame to allow for better integration with institutional timelines, which often require an annual review or progress report, and a longer timeframe to put new institutional guidance documents, manuals, and training, into place. We urge NIH to allow currently approved protocols to be considered compliant for the original duration of the approval, so that ongoing research that newly enters the scope of a revised policy will not be disrupted or paused while waiting for evaluation and approval. Additionally, many institutions have noted that a change to a de novo registration submission for the protocol after three years will cause administrative burden without any added benefit. We would recommend that these be changed to a resubmission, similar to the current process for IACUC protocols.

While additional flexibility for and empowerment of Institutional Biosafety Committees (IBCs) is

appreciated, there are components of the draft policy which should be amended to allow for even more streamlined IBC management and operations. It is helpful for NIH to share the necessary elements of meeting minutes, but institutions noted that issuing a required template increases, rather than decreases, administrative burden. Many IBCs do not run their meetings in the same way, and the lengthy template can create obstacles with the software systems used to support this process. With respect to the proposed requirement to post meeting minutes online prior to the next meeting, we recommend that the requirement instead be "within 30 days of the meeting," as IBCs from different institutions meet at different frequencies. A 30-day time frame for all institutions would allow sufficient time for review and posting.

AAMC agrees with the NIH that transparency is a key component of biosafety research, and further notes that transparency must be balanced with the safety of the individuals conducting and overseeing this research, the security of research facilities, the necessity to maintain confidential information, and the ability to have procedures in place which facilitate open reporting at the institution. Public posting of incident reports may discourage investigators from reporting incidents to the institution and also present safety concerns for these labs and researchers. Given that the focus and primary goal is for the institution to be made aware of these incidents and for NIH to receive this information and take any appropriate action, we recommend that incident reporting continue to be communicated directly to the agency, without a requirement for public posting. If the public posting requirement is retained, we strongly urge NIH to list specific elements of the reports that may reasonably be redacted from publicly-posted records to preserve the security and privacy of scientists, staff, and the laboratories in which they work. Finally, we recommend that the Annual Incident Summary Report from NIH should preserve institutional anonymity, where appropriate, to prevent public identification and potential targeting of any individual institution.

6. Other feedback relevant to this resource: We additionally appreciate the NIH's acknowledgement that "resources and guidance will be required to achieve successful implementation of a modernized biosafety policy." This point was reiterated by all institutions, with the following specific comments on what would be helpful from the agency: NIH should provide further information on expected components for the training for investigators and IBC members; NIH should list the required elements for the IBC registration form and biosafety assurance from an institution; and it would be helpful for NIH to provide additional clarification of the terms "GDMO," "well-characterized cell lines," and "low-risk transgenes."

Uploaded File: AAMC-Comments-NIH-Draft-Biosafety-Policy.pdf

Description: AAMC Comments re: NOT-OD-26-112

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October 19, 2026

Office of Science Policy
National Institutes of Health
Bethesda, MD 20892

Re: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Submitted via https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

The AAMC[1] appreciates the community outreach that NIH has engaged in over the past year as part of the efforts to modernize the NIH Guidelines and strengthen biosafety oversight. We strongly support the development of a biosafety policy which is reflective of the significant progress in science and can effectively address any evolving challenges in conducting work with biohazards and other agents.

In discussions about the draft biosafety policy with AAMC member institutions, we heard often that the academic medical community has had difficulty in providing a comprehensive response to NIH prior to the release of the implementation guidance for the recently issued United States Government Policy for Stopping High-Risk Life Sciences Research.[2] Institutions largely manage their biosafety and potential dangerous gain-of-function (DGOF) projects through overlapping processes and specialized staff. To address these concerns, we recommend that the NIH Office of Science Policy open a public comment opportunity for a minimum of 60 days after the release of the DGOF

[1] Established in 1876, the AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 163 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; more than 400 academic health systems and teaching hospitals; and more than 70 academic societies. The AAMC also collaborates with the Department of Veterans Affairs (VA) and VA medical centers through their academic affiliations with AAMC-member institutions. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 220,000 full-time faculty members, 100,000 medical students, 167,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

[2] USG Policy for Stopping High-Risk Life Sciences Research. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-101.html

implementation guidance to allow for further feedback on the biosafety policy, including potential conflicts or additional regulatory burden that would arise in the implementation of the two policies. AAMC remains concerned about the breadth of the DGOF policy, which could dramatically impede the research timeline while an institution reviews all proposed applications for potential DGOF through a new administrative process.

The AAMC urges that as NIH develops the biosafety policy, the agency prioritize harmonization not only with other NIH policies but with other federal research agencies. In particular, many NIH grantees are also conducting research with plant pathogens and are subject to requirements from the U.S. Department of Agriculture (USDA). The NIH and USDA should ensure a coordinated approach to addressing biosafety issues through policies and regulations.

The draft policy proposes a six-month implementation timeframe, which would be challenging for institutions. The AAMC recommends that NIH adopt a one-year implementation time frame to allow for better integration with institutional timelines, which often require an annual review or progress report, and a longer timeframe to put new institutional guidance documents, manuals, and training, into place. We urge NIH to allow currently approved protocols to be considered compliant for the original duration of the approval, so that ongoing research that newly enters the scope of a revised policy will not be disrupted or paused while waiting for evaluation and approval. Additionally, many institutions have noted that a change to a *de novo* registration submission for the protocol after three years will cause administrative burden without any added benefit. We would recommend that these be changed to a resubmission, similar to the current process for IACUC protocols.

While additional flexibility for and empowerment of Institutional Biosafety Committees (IBCs) is appreciated, there are components of the draft policy which should be amended to allow for even more streamlined IBC management and operations. It is helpful for NIH to share the necessary elements of meeting minutes, but institutions noted that issuing a required template increases, rather than decreases, administrative burden. Many IBCs do not run their meetings in the same way, and the lengthy template can create obstacles with the software systems used to support this process. With respect to the proposed requirement to post meeting minutes online prior to the next meeting, we recommend that the requirement instead be "within 30 days of the meeting," as IBCs from different institutions meet at different frequencies. A 30-day time frame for all institutions would allow sufficient time for review and posting.

AAMC agrees with the NIH that transparency is a key component of biosafety research, and further notes that transparency must be balanced with the safety of the individuals conducting and overseeing this research, the security of research facilities, the necessity to maintain confidential information, and the ability to have procedures in place which facilitate open reporting at the institution. Public posting of incident reports may discourage investigators from reporting incidents to the institution and also present safety concerns for these labs and researchers. Given that the focus and primary goal is for the institution to be made aware of these incidents and for NIH to receive this information and take any appropriate action, we recommend that incident reporting continue to be

communicated directly to the agency, without a requirement for public posting. If the public posting requirement is retained, we strongly urge NIH to list specific elements of the reports that may reasonably be redacted from publicly-posted records to preserve the security and privacy of scientists, staff, and the laboratories in which they work. Finally, we recommend that the Annual Incident Summary Report from NIH should preserve institutional anonymity, where appropriate, to prevent public identification and potential targeting of any individual institution.

Many institutions already review all research on their campus that falls under the current NIH Guidelines, and some with an even broader scope. However, while many institutions voluntarily review this research, we do not believe that there is statutory authority for the agency to require that this policy be applied to non-NIH funded research that is conducted at an institution that receives any NIH funding. We urge NIH to limit this policy's application to NIH-funded research to avoid the situation in which this policy has a fundamentally different scope and reach than any similar policy from NIH or other science funding agencies.

Generally, many institutions appreciate that the draft policy is adaptable and reflects the evolving nature of science. However, the broadened scope of the policy combined with a lack of details about its application, adds a substantial amount of low-risk research to the review and oversight process without guidance on which, if any, projects should be exempt from this policy. The policy as currently written could require investigators to register, for example, every plasmid, gene target, and well-characterized cell line, which would be enormously burdensome and divert resources from thorough evaluation of high-risk research. Importantly, this outcome would not align with the NIH's goal of "removing red tape for low-risk research." We propose that the policy identify specific categories of low-risk research or protocol amendments which are not subject to IBC and/or NIH review.

The draft policy is not clear on how delegated review might relieve some of the burden added by the new requirements. We recommend that any oversight required for routine activities, such as the use of low-risk transgenes in cell culture, should be minimal, requiring only that the institution records that this general category of work is occurring and ensures that the appropriate training, facilities, containment, and safety practices are in place.

In conversations with AAMC member institutions, we heard consistent support for the continued use of Risk Group classifications as a baseline for risk assessment, with several comments that the use of these groups is critical and allows for more flexibility based on the research due to its focus on the properties of the agent in question. Biosafety levels were identified as being an important part of a comprehensive risk assessment and determination of the containment levels needed, depending on any changes to the risk level from the specific research being done.

We additionally appreciate the NIH's acknowledgement that "resources and guidance will be required to achieve successful implementation of a modernized biosafety policy." This point was reiterated by all institutions, with the following specific comments on what would be helpful from

the agency: NIH should provide further information on expected components for the training for investigators and IBC members; NIH should list the required elements for the IBC registration form and biosafety assurance from an institution; and it would be helpful for NIH to provide additional clarification of the terms “GDMO,” “well-characterized cell lines,” and “low-risk transgenes.”

Biomedical research involving potential biohazards is critical to our understanding of infectious diseases and emerging health threats, and an essential component of the public health enterprise in the United States. Federal regulations and policies addressing biosafety for this research should ensure it is conducted ethically and with appropriate oversight and training but not impede the ability to do this research, which can be extremely time-sensitive in the event of immediate threats. Any biosafety policy should not impede scientific progress or our ability to anticipate and respond to health and environmental risks in collaboration with the necessary scientific partners.

AAMC is strongly in support of the NIH’s goals to “augment public safety, transparency, and accountability in its stewardship of the biomedical research enterprise” and look forward to NIH’s continued engagement with the research community as it finalizes the biosafety policy. We would be pleased to provide additional information or clarification on any of the recommendations in these comments. For questions, please contact Anu Dev, PhD, Director, Science Policy and Strategy (adev@aamc.org).

Sincerely,

[redacted]
Elena Fuentes-Afflick, MD, MPH
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer

401. University of Nebraska-Lincoln

I am responding: On behalf of an organization

Name:

Name of Organization: University of Nebraska-Lincoln

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: a) We support the 4-year timeframe for submittal of a written Biosafety Assurance. However, minimum expectations for attaining NIH approval must be detailed to provide consistency from one institution to another.
b) We support re-registration of IBC protocols after 3 years from initial approval but suggest that the 3-year period be from either initial registration, re-registration, or amendment.
c) We support the emphasis on risk assessments with flow of the process from PI to IBC.
d) The scope of the policy should be clarified with consideration of NIH's mission and titled in a manner that reflects that scope.
e) At times, the policy references risk to human health as a threshold (i.e., section titled "Scope") and other times reference is made to human disease (i.e., definition of biological agent). These are very different concepts which makes it difficult to determine applicability of the policy to plant pathogens, GMO plants, animal pathogens that do not cause disease in humans, GMO animals, etc. For example, an animal pathogen that does not cause disease in humans may pose threat to human health if its uncontrolled spread in agriculture threatens the food supply and/or economic impact.
f) Likewise, the terms "biohazard" and "biological agent" are used inconsistently throughout the policy. The definitions do not contain the term "biohazard." These terms should be defined and used in a deliberate fashion throughout the policy to provide clarity. Furthermore, the definition for biological agent contained in the policy is not consistent with the broadly recognized definition of biological agent within the research community, which will likely lead to confusion and inconsistency in applying the policy. Consideration should be given to using the term "hazardous biological agent" or some uniquely coined term and defining such.
g) The Scope of the policy references "potential risk to human health" but gives no threshold for potential risk. The threshold should be clarified. Is it a substantial potential, reasonable potential, any potential? We encourage adoption of the following threshold: "an assessment of an outcome such that, generally, individuals with scientific expertise relevant to the research in question would expect this outcome to occur but exclude experiments in which experts would anticipate the outcome to be technically possible, but highly unlikely."
h) We encourage consideration of a threshold for toxins for inclusion within the scope of the policy,

which could be based on level of toxicity such as LD50 and aggregate amount on hand or in process at any given time.
i) Within the definition of Genetic Modification, we encourage limiting the second bullet to the germ line of multi-cellular organisms to avoid overly broad application of the policy. Of particular concern is inclusion of chemical or radiological means and the absence of discussion or limitiation of genetic alterations that result in biological hazards and resultant risks.
j) The current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules provide greater clarity on containment requirements as it relates to genetically modified organisms. The draft policy does not address setting of appropriate containment levels for research involving genetically modified organisms, particularly when genetic material from a higher risk group organism is transferred to a non-pathogenic or lower risk group organism. Related provisions in Section III-D of the existing Guidelines should be incorporated into the new policy. Furthermore, the draft policy should be modified to explicitly address setting containment levels for biological agents that are not human pathogens, assuming such is within the scope of the policy, and the need or lack thereof for petitioning the NIH to set the containment level. It should also be clarified that Risk Group is one consideration in selecting the final containment level and, while complementary, risk group and containment level are not synonymous or interchangeable.
k) We encourage that the policy specifically exempt those experiments currently described in Section III-F of the current NIH Guidelines.
l) We encourage that the policy specifically include those experiments currently described in Section III-E of the current NIH Guidelines into Section IV-3 of the proposed policy. Furthermore, the term “minor amendment” in Section IV-3 of the draft policy should be defined.
m) The draft policy represents a significant departure from the current NIH Guidelines and greatly expands the scope and reach of the policy. Compliance with the draft policy will require a complete rebuilding of institutional programs, policies, training, oversight, and review of research proposals, as well as analysis and review of existing research. A six-month implementation deadline will not be feasible for most research institutions. We encourage extending the effective date for a minimum of 18 months, with the caveat that institutions continue to comply with the existing NIH Guidelines and applicable Executive Orders until they have established policies and procedures consistent with the revised policy. Furthermore, allowance for a graduated approach is needed to prevent everything from being due at the same time, which would also extend to future protocol re-submissions, Biosafety Assurances, and other requirements in the policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: We support recognition of the BMBL when setting containment levels and encourage expansion to recognize containment levels set by other federal agencies as a permit condition (such as USDA APHIS and CDC VS permits). However, the NIH must clearly distinguish portions of the BMBL that are considered mandatory and those that are considerations when selecting alternatives for specific research applications. Further, we encourage allowing institutions to set containment for biological agents that present low risk based on literature review rather than requiring petitioning of the NIH to set containmnet.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: a) We oppose the requirement to publicly post incident reports when such reports are available under the Freedom of Information Act or equivalent state legislation. Such a requirement, particularly when it does not involve a significant threat to human health or the environment, will unnecessarily deter reporting. Further, we do not support inclusion of the name of the Principal Investigator or grant identifying information in the incident report.
b) We also ask for clarification of the requirement to post IBC meeting minutes (and incident reports if that requirement remains) "on a pubic-facing webpage on the website of the institution (p.5, bullet 2, under the heading of "IBC Functions)." We encourage this to not mean the main landing page of an institution, but rather a sub-website where all other IBC information is posted and which is readily accessible to the general public.

6. Other feedback relevant to this resource: a) Does the definition of laboratory research and the statement in Section II (research conducted within BSL.ABSL 1-4 containment spaces…) apply to the research project or the facility where the project is conducted?
b) We are concerned with lack of details regarding "BSL3 enhanced containment for HPAI H5N1 work" (Section V-E). Specifically, what is meant by "enhancement"? We think a definition of enhancement must be included in this document.
c) NIH should clarify how institutions are expected to integrate risk assessments, mitigation measures, oversight conditions and reporting obligations when the same research activity is subject to both the NIH Policy for Research Involving Biohazards and the USG Policy for Stopping High-Risk Life Sciences Research.
d) The definitions contain separate definitions for "biomedical research" and "laboratory research" yet the term "laboratory research" does not appear in the policy other than as a definition.
e) Section III-B (Responsibilities of the Institutional Biosafety Committee), Subsection Titled "IBC Functions", first bullet, states that the IBC is responsible for …. (1) independent risk assessment of the biocontainment levels required for the proposed research…. We suggest that this statement be modified to indicate that the IBC is responsible to review and approve or request changes to the Principal Investigator's initial risk assessment rather than mandating an independent risk assessment.
f) Section III-B (Responsibilities of the Institutional Biosafety Committee), Subsection Titled "IBC Functions", bullet 10 requires reporting of "certain incidents to the NIH that pose significant risk to human health" within 24 hours and goes on to state that these reporting requirements include incidents that involve a number of situations (such as Laboratory Acquired Infection, loss of containment, etc.). However, the last bullet of this list is "any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approval, or failure to obtain NIH approval for lowering biocontainment research, when required." This last bullet does not necessarily rise to the threshold of "pose significant risk to human health" and should be a separate reporting requirement with a greater reporting period, as currently required under the existing NIH Guidelines.
g) Implementation guidance in all areas is critical to the effective implementation of the proposed policy. We encourage guidance similar in nature to that which was provided for the former DURC/PEPP USG policy.

402. Stephanie Adams

I am responding: On behalf of myself

Name: Stephanie Adams

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Professional - Why is there NO Role entry for this!!!!! It just shows.

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: In "Section IV-3. "
The individual must be an Biosafety professional, who can review and approve all amendments for minor changes or if the registration is for the use of :
Research involving RG2 wild type biological agents.
Research with genetically modified RG1 biological agents [Note: Experiments involving RG1 wild-type biological agents are not subject to this Policy].
Research conducted with transgenic organisms at BSL-1/ABSL-1.
Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes.
Research with well-characterized cell lines.
Research with biological toxin proteins not on the Select Agent list.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The Draft Policy also places significant responsibilities on biosafety officers (BSOs), Institutional Biosafety Committees (IBCs), and institutions, but it fails 2 Comments on NIH Biosafety Policy to empower them to carry out these responsiblities with sufficient independence and authority, along the lines that institutional review boards (IRBs) and institutional animal care and use committees (IACUCs) do under their governing regulations.

Biosafety officer and IBC committee must be given resources and funding to actually be able to do the work.

Not everyone is qualified to serve as a Biosafety Officer. At a minimum, a Biosafety Officer should have at least two years of laboratory or clinical experience and three years of dedicated biosafety experience.

Every IBC committee must have at least 2 Biosafety Officers on their committee to ensure correct mitigation practices that also align with the whole institution.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: We cannot name anyone on the incident reporting. This can become a HIPAA violation.

6. Other feedback relevant to this resource: N/A

Uploaded File: COGR_AAU_APLU-Letter-to-NIH-on-Proposed-Biosafety-Policy.pdf

Description: AAU and COGR letter shows very well how this draft can be imrpoved.

October 16, 2026

Via Email to: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/.

National Institutes of Health
Office of Science Policy
Attn: Cari Young, Sc.M., Director of Biosafety, Biosecurity, and Emerging Bioteechology Policy Division

RE: Response to Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards

To Whom It May Concern:

The Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), and COGR write to offer comments in response to the Draft NIH Biosafety Policy for Research Involving Biohazards (Draft Policy) published in the Federal Register on September 14, 2026. [91 FR 58132].

Founded in 1900, AAU comprises 69 of America's leading research universities that transform lives through education, research, and innovation. Research universities, including AAU members, have a long-standing partnership with the federal government to advance science and technology in the national interest. This partnership, rooted in World War II, has been central to U.S. global leadership in science and technology.

APLU is a membership organization that advances the mission of land-grant and public research universities. Founded in 1887, APLU is the oldest higher education association in the United States. Its U.S. membership consists of more than 240 land-grant and public research universities, state university systems, and affiliated organizations spanning across all 50 states, the District of Columbia, and five U.S. territories. The association and its members

collectively focus on increasing student success and workforce readiness; promoting pathbreaking scientific research; and bolstering economic and community engagement. Annually, its U.S. member campuses enroll 4.6 million undergraduates and 1.4 million graduate students, award 1.3 million degrees, employ 1.3 million faculty and staff, and conduct $70 billion in university-based research.

COGR is the national authority on federal policies and regulations affecting U.S. research institutions. We provide a unified voice for over 230 research universities and affiliated academic medical centers and research institutes. Our work strengthens the research partnership between the federal government and research institutions and furthers the frontiers of science, technology, and knowledge. We advocate for effective and efficient research policies and regulations that maximize and safeguard research investments and minimize administrative and cost burdens.

The academic research institutions that AAU, APLU, and COGR represent understand and support NIH's desire to update its current Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines") beyond the changes that were incorporated into those Guidelines in April 2024. Our member institutions are leaders in the conduct of biomedical research and fully support risk-based policies that protect researchers and the public from biohazards, while facilitating conduct of the broad spectrum of life sciences research necessary to ensure America's ability to understand and address threats to individual and public health. They also support regulations that embue biosafety officers (BSOs) and institutional biosafety committees (IBCs) with the power and authority to provide oversight for research involving biohazards.

Unfortunately, the Draft Policy does not callibrate required controls to actual risk presented, particularly in the case of lower-risk research activities. During the stakeholder consultation process, we were encouraged by discussions regarding how the Draft Policy could take a more risk-based approach to regulation. However, the Draft Policy does not retain many of the risk-based features of the NIH Guidelines. Instead, it adopts an overly risk-averse approach that substantially increases institutions' review and oversight responsibilities for low-risk research that was previously exempt.

The Draft Policy also places significant responsibilities on biosafety officers (BSOs), Institutional Biosafety Committees (IBCs), and institutions, but it fails

to empower them to carry out these responsiblities with sufficient independence and authority, along the lines that institutional review boards (IRBs) and institutional animal care and use committees (IACUCs) do under their governing regulations. Instead, the Draft Policy's vast scope (which includes virtually ALL research involving biological agents conducted at any institution that receives NIH funding), coupled with its overly prescriptive and risk averse requirements for IBC review, oversight and reporting functions, will substantially increase administrative burden while diverting limited biosafety resources from higher-risk activities, potentially undermining, rather than increasing, laboratory and public safety. Further, despite requiring institutions to provide review and oversight for non-NIH/non-federally funded research, the Draft Policy provides neither statutory support for these requirements nor mechanisms to reimburse institutions for associated implementation costs. Accordingly, as an overarching comment, we urge NIH to reevaluate both the scope of the Draft Policy and its risk calibration.

Below, are additional general comments regarding the Draft Policy, followed by comments and recommendations on specific policy provisions. In addition, our organizations recommend NIH consider using a notice of proposed rulemaking that includes the statutory basis for the proposed changes and a regulatory-impact analysis to facilitate such an extensive policy change.

GENERAL COMMENTS

▪**Intersection between Draft Policy and United States Government Policy for Stopping High Risk Life Sciences Research ("USG Policy"):** Given the Draft Policy's coverage of "research involving biohazards" and the USG Policy's coverage of broadly defined "Potential Dangerous Gain of Function (DGOF) Research" and "Other Risky International Research," there is substantial potential for overlap between the two policies. Unfortunately, the USG Policy had not been issued at the time that NIH was collecting stakeholder input on the Draft Policy. Further, NIH has not yet issued its implementation guidance for the USG Policy. Thus, institutions do not have any information on how NIH anticipates the Draft Policy will intersect with the USG Policy. Accordingly, it seems premature to collect stakeholder input on the Draft Policy, until NIH is in a position to provide these details.
Recommendation: Our associations urge NIH to extend the final date of the comment period on the Draft Policy to a date that falls at least 60 days after NIH has released its implementation guidance for the USG Policy and provides information on how the two policies intersect.

▪**Scope of Draft Policy Exceeds Statutory Authority:** NIH cites no statutory authority to support extending the scope of the Draft Policy to "non-funded NIH research that is conducted . . . at an institution that receives any NIH funding" ("Funded Institution"). Indeed, the only reference to biological agents and toxins contained in the statute prescribing the NIH director's duties/authorities is a requirement for the director to consult with named federal agencies/offices, "as appropriate, ***regarding research needs*** to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agents that may cause a public health emergency or other research needs related to emerging public health threats." [42 USC §282(b)(26) (***emphasis added***)].
Recommendation: NIH should provide the explicit statutory authority that authorizes it to include within the Draft Policy's scope non-federally funded research conducted at a Funded Institution, or, in the absence of such explicit authority, confine the Draft Policy's scope to NIH-funded research. Further, as noted, given the scope and magnitude of the Draft Policy, NIH should consider issuing the Draft Policy through the federal notice and comment rulemaking process, as opposed to issuing it as an agency policy.

▪**Draft Policy is Not Accurately Risk Calibrated and Places Substantial and Unjustified Administrative and Cost Burdens on Institutions:** Although the Draft Policy claims to support a risk-based approach to the review and oversight of biomedical research, its approach is not accurately risk calibrated. Specifically, the Draft Policy is overly risk-averse because it vastly increases the scope of research requiring IBC and/or NIH review by eliminating categories of low-risk research that were previously exempt from IBC review processes. Further, the Draft Policy's provisions concerning inspections, continuing reviews, and other oversight activities also lack risk calibration and/or are duplicative of oversight efforts in place via other regulatory and institutional mechanisms (e.g., IACUC semi-annual inspections, institutional lab safety inspections).

NIH's failure to "right-size" the draft Policy to the level of risk presented by specific activities results in unnecessary oversight for lower-risk activities, which in turn diverts resources that could be more effectively devoted to managing higher risk research. Further, NIH expects Funded Institutions to perform these responsibilites for ALL non-NIH funded research within the policy's scope. Yet, the policy contains no mechanism to ensure that institutions are fully reimbursed for costs associated with providing these

oversight functions. The Draft Policy also fails to adequately account for the security, privacy, and confidentiality risks created by the mandated public posting of information regarding biosafety procedures, IBC meeting minutes, the conduct of BSL/ABSL-3 or BSL/ABSL-4 research, and incident reports.

Recommendation:

(a) Develop and include within the Draft Policy categories of lower-risk research activities that do not require IBC and/or NIH review.

(b) As previously noted, remove non-NIH funded activities from the Draft Policy's scope. Alternatively, if NIH can demonstate appropriate statutory authority to support its regulation of these actitivies, it should specify within the Draft Policy how institutions will be compensated via NIH funding mechanisms for providing the oversight functions NIH is mandating.

(c) Modify the Draft Policy to permit IBCs to calibrate the type and frequency of oversight activities to actual risks presented by research activities and to coordinate with and prevent duplication of other inspection/review efforts carried out within the institution.

(d) Develop and include with the Draft Policy more detailed research security and privacy factors that institutions can rely upon to support the redaction of confidential and/or senstive private information from minutes and incident reports prior to posting, or alternatively, require only anonymized aggregated reporting.

▪**Draft Policy Uses BMBL in More than an Advisory Capacity:** The foreword to the CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL) explicitly states that it is an "advisory document," and it is not intended to be a "regulatory document." Rather, the BMBL was intended to be a periodically updated guidance document designed to support expert risk assessment and preserve institutional discretion. Despite this caution, the Draft Policy uses the containment levels set forth in the BMBL in a regulatory manner and constricts the IBC's ability to lower containment levels without NIH approval. The fact that the current issue of the BMBL was last revised prior to the COVID pandemic reveals a major flaw in using the BMBL in such a regulatory manner, i.e., the information in the BMBL is not continuously updated to reflect the latest scientific developments.

Recommendation: NIH should clearly state in the Draft Policy that the BMBL remains an advisory document, and as such, the establishment of containment levels by IBCs and NIH will be governed by current scientific evidence and may be higher *or lower* than BMBL-suggested levels when scientifically justified. Our organizations also urge NIH to ensure that there are adequate funding and operational mechanisms in place to continuously

update the BMBL to make certain that the information it contains accurately reflects the current state of scientific knowledge.

▪**Implementation Timeline is Too Short:** The Draft Policy specifies that it will take effect six months from the date of publication of the final policy with respect to new and existing NIH-funded research and non-NIH funded research conducted at an institution that receives NIH funding. The substantial increase in the portfolio of research that must be reviewed under the Draft Policy will place tremendous strain on institutions' existing IBC and biosafety operations and more than six months will be needed to take stock of new categories of research that require review; update institutional policies, processes, procedures, workflows, and associated tools; and train researchers and staff on the new policies/procedures.
Recommendation: Our organizations urge NIH to extend the effective date to 24 months from the date on which the final policy is published to afford institutions adequate implementation time. At a minimum, NIH should extend the effective date by at least 12 months from the final policy's publication date.

▪**Draft Policy is Unclear as to How Genetically Modified Plants will be Addressed:** Unlike the current policy, the Draft Policy does not include genetically modified plants within its framework, elminating a long-standing source of containment guidance for institutions, as well as best practices for greenhouse research, growth chamber research, pollen containment, reproductive isolation, and prevention of environmental release.
Recommendation: NIH should clarify how the government plans to handle guidance regarding genetically modified plants, including whether, NIH or another federal agency, plans on issuing guidance on this topic.

▪**Policy Format is Difficult to Follow:** The Draft Policy's lack of sequentially numbered sections and subsections make it difficult to use and cite.
Recommendation: To improve user friendliness, NIH should sequentially number each section and subsection of the Draft Policy.

SPECIFIC COMMENTS

Section I, Purpose: No comments.

Section II, Scope: See comments below.

▪**Draft Policy's Scope Is Overly Broad and Not Risk-Based:** The Draft Policy applies to "reseach involving known or potential risk to human health" and any of the items listed in provisions 1-4 of the Scope Section, including "[c]ells or organisms, other than plants," containing any of the items listed in items 1-3 of the Scope Section. However, virtually all organisms/cells contain some level of microorganismal contaminination. Further, there is no universal screening process for human pathogens, and some bacteria/microorganisms pose risk to only limited segments of the population (e.g., immunocrompomised individuals). Thus, as written, the Draft Policy **essentially treats every biological agent as a biohazard**, and by doing so it applies **to virtually any organism, with the exception of plants, without regard to actual risks presented. This approach serves to divert institutional/IBC time and resources to the assessment and review of lower-risk biomedical research and unnecessarily impedes the conduct of such research.**
Recommendation: To truly make the Draft Policy risk-based, we urge NIH to limit its scope to cells or organisms, other than plants, that contain one of the items in provisions 1-3, and that are known, or likely to cause, disease in humans. For example, certain toxins and self-aggregating proteins may not pose risk to human health in the absence of LD50 thresholds and/or clear evidence of causation of disease/harm. We also urge NIH to establish categories of lower-risk research such as research conducted at BSL-1/ABSL-1 that are excluded from the scope of the policy and/or are exempt from IBC or NIH review.

▪**Items within the Scope Section that Require Clarification:** The following provisions within the scope section are confusing and would benefit from additional clarification:

- **Laboratory Settings:** The term "laboratory settings" should be defined and distinguished from the defined term "laboratory research." Specifically, the Scope section states that the Draft Policy covers "all biomedical research, in ***laboratory settings,*** involving biohazards," [***emphasis added***] but the terms "laboratory settings" and "biohazards" are not defined. Instead, the Draft Policy defines the term :"Laboratory Research" as research conducted in BSL/ABSL 1-4 containment facilities. Accordingly, the scope of the policy is unclear. For example, are arthropod containment facilities, insectaries, or greenhouses considered to be "laboratory settings"? Does the Draft Policy apply to field research?
- **Clinical Research:** It is also unclear how the Draft Policy applies to clinical research, which is traditionally subject to other oversight mechanisms (e.g., OSHA bloodborne pathogen standard, hospital

infection control committee requirements). As previously noted, the policy defines Laboratory Research in terms of research conducted at BSL/ABSL levels in containment facilities but goes on to note that clinical research does not utilize traditional biosafety levels. Indeed, the only guidance the Draft Policy provides regarding risk assessment/mitigation in clinical settings is that "precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection."

Recommendation: NIH should clarify when and how the Draft Policy applies to research conducted in clinical settings. Additionally, our organizations recommend that risk assessment/mitigation in clinical setting utilize universal precautions as a baseline, coupled with additional controls (e.g., transmission precautions) based on hazard characteristics and routes of transmission associated with the items being studied. Along these same lines, NIH should clarify IBC review requirements for clinical research under Section IV.2, and detail how they intersect with other requirements in clinical settings (e.g., OSHA bloodborne pathogen requirements, hospital infectious control requirements, etc.).

- ***In Silico* Research:** The Draft Policy is unclear as to whether *in silico* research on items listed under provisions 1-4 of the Scope Section falls under the policy's auspices.

Recommendation: NIH should clarify whether *in silico* research on items listed under provisions 1-4 of the Scope Section does/does not fall within the scope of the Draft Policy, because such research does not necessarily involve a known or potential risk to human health.

- **Applicabilty to Lower-Risk Research Activities:** The draft policy is limited to "research involving known or potential risk to human health." This limitation suggests that the Draft Policy should not apply to certain lower-risk reseach (e.g., RG1 recombinant materials, gene drive modified organisms (GDMOs), and transgeneic animals at BSL-1/ABSL-1). However, several sections of the Draft Policy appear to require institutional registration and review of these lower-risk research activities without sufficient explanation and support for such risk calibration.

Recommendation: Given that NIH intends for the Draft Policy to be risk-based, NIH should specify those categories of lower-risk research activities that are excluded from the policy's scope. If all biomedical research involving the use of biological agents is included within the

Draft Policy's scope, then institutions will be required to devote a huge amount of time and resources to reviewing and providing oversight for low-risk research activities, in exchange for limited benefit in terms of improved safety.

°Examples of Activites Included/Excluded from the DRAFT POLICY: The Draft Policy does not include examples of research that do/do not fall within the policy's scope.
Recommendation: It would be very helpful to institutions if NIH provided concrete examples of research that is (a) within the Draft Policy's scope; and (b) excluded from the Draft Policy's scope. It would also be helpful to institutions if NIH clarified whether/how the Draft Policy applies to animal pathogens and other zoonotic risks, agricultural pathogens, plant pathogens, phages, environmental organisms, prions, and other self-aggregating proteins.

°Research Regulated by Other Federal Agencies: The Draft Policy states: "Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained."
Recommendation: It would be very helpful to institutions if NIH could provide details on how this approval/clearance process will work, including:

- Specifying which federal agencies will have authority over various types of pathogens (e.g., Will USDA have jurisdiction over plant pathogens and genetically modified plants?) and what process institutions will need to follow to determine who has jurisdiction.
- Specifying which agency will have ultimate oversight of biomedical research in areas where multiple agencies (e.g., CDC, OSHA, USDA) have overlapping oversight responsibilities, and how that determination will be made.
- Clarifying the meaning of the phrase "approvals or other applicable clearances" and from which agency (i.e., NIH or another federal agency) institutions are expected to obtain these approvals/clearances.

Section II, Compliance and Enforcement: No comments.

Section II, Voluntary Compliance: No comments.

Section II, General Definitions Section

▪**Overarching Comments:** Several key definitions are overly broad, thus creating uncertainty regarding the Draft Policy's scope and undercutting NIH's stated goal of a risk-based biosafety policy. Additionally, the Draft Policy redefines terms that have well-established scientific meaning, reducing the clarity and consistency needed for effective policy implementation.
Recommendation: NIH should ensure that terms are defined in line with their common usage, and revise overly broad definitions to directly align oversight requirements with actual risks presented. Comments regarding specific definitions follow.

▪**Comments on Specific Definitions:**
°**Biological Agent:** As previously noted, the Draft Policy appears to assume that every biological agent constitutes a biohazard, and definitions clarifying the boundaries between these two terms should be provided. Additionally, the term "parasite," as used in this definition, would benefit from further clarification. For example, parasites could encompass mosquitos, ticks, lice, various helminths, etc., so if the definition is referring to intracellular parasites, it should state so. Similarly, the definition should address whether it encompasses ectoparasites that serve as vectors of disease transmission, as opposed to causing disease. Finally, the definition should also be clear as to how "opportunistic pathogens" that only affect very specific segments of the population should be addressed.
Recommendation: Revise this definition to address the points outlined above.

°**Biomedical Research:** In addition to being extremely broad, this definition has the potential to introduce instability and inconsistency, as it refers to "research on a topic that is within the mission of the NIH," and thus could change dramatically over short periods of time, depending on how Congress and the Executive Branch expand or curtail NIH's mission.
Recommendation: NIH should employ a static definition of biomedical research (e.g., "Research that is conducted to increase fundamental knowledge and understanding of the physical, chemical, and functional mechanisms of human life processes and diseases"[1]) that is not tied to, and does not change with, the scope of NIH's mission.

°**Emerging Agent:** NIH's definition of this term is at odds with the definition

[1] Definition of "biomedical research," NIH, Collection Development Guidelines of the National Library of Medicine (2019; updated Sept. 25, 2025).

used by scientists, biosafety, and public health professionals, who consider an "emerging agent" to be a known agent that is emerging as a cause of disease. Further, the NIH definition inappropriately equates a newly identified organism with a pathogen.

Recommendation: NIH should replace this definition with the more commonly accepted definition outlined above. If NIH retains the current definition, it should explicitly define what "newly identified in nature" means. For example, is "newly identified" limited to a new species or genus? Additional points that should be clarified in the definition include the following:

- How would chimeras and plasmids/viral vectors/replicon systems containing genetic material from different sources be viewed?
- How are prions and self-aggregating proteins viewed?
- Does the definition encompass synucleins and preformed fibrils, or other organisms/materials on which there is not yet consensus on whether they cause human disease or are just associated with such disease?

°Genetic Modification: The proposed definition of genetic modification significantly broadens the scope of items covered by the Draft Policy. Specifically, expanding the definition of "genetic modification" to include nucleic acids that can be translated, as well as the alteration of the genome using chemical or radiological means, is inconsistent with the NIH Guidelines' historical approach to oversight of research that introduces stable genetic modifications. Genetically modified organisms **do not** inherently present greater uncertainty. In fact, many genetically modified organisms are well characterized and **present less uncertainty** than their wild-type counterparts. Indeed, the level of uncertainty associated with an organism depends on multiple factors, including the nature of the modification, the amount and quality of available data, the resulting phenotype, and prior experience with the organism. Additionally, the Draft Policy's overly prescriptive approach to genetic modifications will result in inconsistent and duplicative oversight (e.g., overlap with FDA and existing laboratory oversight requirements) and adds little to no value in terms of improved biosafety. Rather, this approach has the potential to increase risk by causing the IBC and biosafety team to "spread themselves thin" by expending time and resources on lower-risk activities, instead of focusing on research presenting higher risks.

Recommendation: NIH's new approach to viewing all genetic modifications as suspect is inconsistent with NIH's intent to develop a risk-based policy. NIH should instead incorporate into the definition of genetic modifications a provision that limits IBC review and oversight to only those genetic

modifications that present specific risk characteristics and/or consequences based on available evidence.

°**Laboratory Research:** The Draft Policy includes the terms "laboratory settings" and "laboratory research," but only provides a definition for "laboratory research," which it defines in terms of containment levels.
Recommendation: As previously noted, NIH should include a definition of "laboratory settings," a term used in the Scope Section. Our organizations also recommend that NIH clarify whether the scope of the policy is based on "laboratory settings" or 'laboratory research." Finally, given that not all "laboratory research" requires containment levels, NIH should consider renaming this term as "laboratory research requiring containment" to avoid causing confusion among scientists and biosafety personnel who commonly understand this term as any research taking place in a lab setting.

°**Research Involving Biohazards:** This term is defined in the scope section, but it does not appear in the general definitions section.
Recommendation: For consistency, NIH should include "research involving biohazards" as a defined term within the general definitions section and specify how the term relates to the setting in which such research is performed, i.e., laboratory settings.

°**Toxins:** The Draft Policy defines a "toxin" as: "[a] protein or peptide produced by living organisms that causes harm in humans." Many biological molecules may cause harm under certain exposure conditions or at sufficiently high concentrations, but absent such conditions, they may be harmless. Although the risk assessment section of the Draft Policy appropriately accounts for factors such as potency, amount used, and intracellular accessibility, these concepts are absent from the definition. Additionally, the definition does not address the potential of exceptions for naturally occurring toxins (e.g., those produced by algae, use of cephalopods, etc.).
Recommendation: NIH should incorporate objective criteria (e.g., potency, exposure potential, quantity, biological activity) into the definition of "toxin," and consider using LD50 levels as a criterion for inclusion under the Draft Policy.

Section III, Roles and Responsibilities: See comments below.

Section III-A, Responsibilities of the Institution

▪**Applicability:** As previously noted, extending the Draft Policy to non-federally funded research conducted at institutions that receive any NIH funding appears to exceed the scope of NIH's regulatory authority.
Recommendation: NIH should identify the specific statutory authority supporting the extension of the Draft Policy to non-federally funded research conducted at institutions receiving NIH funding, and absent such specific authority, limit the scope of the Draft Policy to NIH-funded research. NIH should also provide greater clarity in this section and/or in the scope section regarding exactly what entities the policy applies to (e.g., affiliated hospitals, separately incorporated research institutes, subcontractors, international sites).

▪**Biosafety Assurance:** It is imperative that Authorized Organizational Representatives (AORs) specifically understand the criteria to which they are certifying through their execution of the Biosafety Assurance. It is also important that NIH conduct the assurance process in an efficient and streamlined manner that permits institutions to begin/continue covered research without undue delay.
Recommendation: NIH should clarify the following issues in the Draft Policy:

- Is the AOR certifying that the institution has established an adequate biosafety oversight program, or certifying compliance for every individual research activity and researcher covered by the policy?
- Describe the criteria NIH will use to approve, restrict, suspend, or withdraw an Assurance.
- Provide an anticipated turn-around time for NIH' approval of an assurance.

NIH should consider patterning the Biosafety Assurance process after the assurance processes in place at the HHS Office of Human Research Protections or at the Office of Research Integrity. Additionally, it would be helpful to institutions if NIH were to provide a draft template assurance document on which institutions can submit comments.

▪**IBC Training Responsibilities:** The Draft Policy states that an institution is responsible for ensuring appropriate training regarding laboratory safety and implementation for the IBC Chair and members, biological safety officer and other containment experts, principal investigators, and laboratory staff.
Recommendation: NIH should develop and provide role-based training resources that IBCs may use to satisfy these training responsibilities.

▪**Record-keeping requirements:** The Draft Policy vastly expands the scope of research requiring IBC review/oversight, resulting in a tremendous increase in IBC-associated records (both paper and electronic) that must be developed and retained, at substantial storage and archival costs.
Recommendation: NIH should consider implementing a more limited period of record retention. Given that the Draft Policy calls for the IBC to provide *de novo* review of each research protocol every three years, our organizations suggest that NIH cap the record retention period at two review cycles (six years), thus affording transparency, while reducing administrative burden.

▪**Public Posting of IBC Related Documentation:** The Draft Policy calls for the institution to publicly post "to the maximum extent possible" the following documents/information:

- Weblinks to publicly posted institutional biosafety procedures (including but not limited to documentation detailing the IBC roles, responsibilities, authorities, and processes for how biosafety risks are managed);
- A continuously updated IBC roster;
- IBC meeting minutes;
- Incident reports;
- Synopses of relevant staff trainings provided;
- Contact information for the IBC Contact, IBC Chair, and BSO (if applicable); and
- Information regarding whether the institution conducts research in a BSL3/ABSL-3 or BSL4/ABSL-4 laboratory, research with GDMOs, has a BSO, receives NIH funding, and/or has an externally administered IBC.

This approach fails to strike an appropriate balance between the need for public transparency and the need to protect the security of laboratory facilities, the security and privacy of biosafety personnel, and proprietary and confidential information associated with non-federally funded research that now falls within the scope of the Draft Policy.
Recommendation: Our member institutions understand the need for required documentation retention for agency inspection as appropriate under the Draft Policy. Nonetheless, the need for public transparency must be balanced against the goals and requirements of privacy laws (e.g., HIPAA, state privacy laws, collective bargaining agreements) and other policy concerns (e.g., protection of trade secrets, promoting a just and fair culture of incident reporting). With respect to incident reports, which often contain sensitive personal information, NIH should permit anonymized, aggregated reporting with identifiable information disclosed to appropriate governmental officials

only when there is a legitimate need to know (e.g., public health investigation). If NIH declines to adopt anonymized/aggregated reporting, it should not require the posting of any personally identifiable information except for the names and institutional information for the IBC Contact, IBC Chair and BSO.

NIH should also specify within the Draft Policy a de-identification standard (e.g., HIPAA standard) and specify what information can be redacted from records prior to public posting to protect the security and privacy of biosafety personnel and facilities and to safeguard proprietary and confidential information associated with non-federally funded research. Further, NIH should also exempt from posting any information related to processes and procedures developed to ensure the security of covered research and the facilities in which that research is conducted. Finally, the Draft Policy should be exempt from posting any information designated as confidential or proprietary by non-federal research sponsors.

Section III-B, Responsibilities of the Institutional Biosafety Committee

▪**Overarching Concerns:** Although NIH has expressed its intent to elevate and strengthen the role of the IBC and the BSO, the Draft Policy does not clearly delegate to those parties the specific authorities necessary to carry out those responsibilities.
Recommendation: NIH should clearly delineate within the Draft Policy specific authorities of the IBC and BSO (e.g., ability to take timely action to address significant biosafety concerns, suspend research protocols, etc.). NIH should also include provisions within the Draft Policy that ensure the IBC's independent decision-making authority akin to the independent authority of IRBs and IACUCs (e.g., institution cannot reverse IBC's non-approval or suspension of a protocol).

▪**IBC Membership**: No comments.

▪**IBC Functions:** See comments below.

▪**First Sentence of Section ("The IBC, or its delegate as applicable, is responsible for"):** The first sentence's reference to "[t]he IBC, or its delegate as applicable" is confusing.
Recommendation: NIH should clarify whether the term "or its delegate" refers to an individual or subgroup of IBC members assigned to conduct "delegated reviews" under Section IV-3.

- **First Bullet Point:**
  - **Clause (3)("in cases of research involving. . . "):** The concerns noted in clause (3) relating to research involving "human subject research participants" are also applicable to animal research.
    Recommendation: Delete the text that reads "in cases of research involving human research participants."

  - **Third Sentence ("IBC oversight may conclude . . . "):** Shedding may continue after the last dose of a product is administered to human research participants, so it is unclear as to why IBC oversight should end at that point.
    Recommendation: Delete the third sentence ("IBC oversight may conclude after the last participant is administered the final dose of product") and modify the fourth sentence to read as follows: "IBCs should establish appropriate endpoints for oversight based on their biosafety assessment of the proposed research."

  - **First Sub-Bullet Point ("No member of the IBC . . . "):**: It is unclear as to who has the responsibility for determining whether an IBC member has a conflict of interest.
    Recommendation: NIH should include a statement that the IBC is empowered to establish its own processes and procedures for soliciting information from members regarding possible conflicts of interest and determining when such conflicts exist and require member recusal.

- **Second Bullet Point ("Taking IBC meeting minutes. . . "):** Requiring approval of IBC minutes "no later than [the IBC's] next convened meeting," places excess administrative burden on IBCs that meet frequently and review large numbers of protocols. Indeed, one COGR member institution has estimated based on current meeting-minute preparation time and the template content that it will be required to hire a full-time employee just to fulfill the Draft Policy's IBC meeting minutes requirements.
  Recommendation: NIH should extend the period for approval of IBC meeting minutes to "no later than ninety (90) days after the meeting at which the minutes were taken."

- **Third Bullet Point ("Notifying the PI when . . . "):** The Draft Policy calls for "de novo registration submission and review" at least every three years, however, NIH does not provide any rationale for requiring de novo review for all protocols or for selecting a three-year period, as opposed to four or five-year

period. If the Draft Policy is intended to be risk-based, then the period for review and re-registration should be based on risk posed by the research in question, as determined by the IBC.
Recommendation: NIH should modify the Draft Policy to permit the IBC to establish the re-registration period based on the risk posed by a specific research protocol. NIH should also empower the IBC to provide a re-review/re-registration grace period of up to 90 days to accommodate circumstances in which the IBC cannot complete its review within the specified period.

Alternatively, if NIH maintains the strict three-year re-registration/re-review period, it should specify within the policy what the status of a protocol is that (a) has not been reviewed/approved within the three-year period; or (b) has been reviewed but not approved within the three-year period because protocol changes are required. Additionally, NIH should clarify whether the three-year review requirement will apply prospectively (i.e., to protocols first approved by the IBC after the Draft Policy is implemented), or retrospectively (i.e., to protocols first approved by the IBC prior the Draft Policy's implementation), and if the latter, the date by which existing IBC-approved protocols must receive de novo approval.

▪**Fifth Bullet Point ("Petitioning NIH for determination of the minimum . . ."):** The circumstances in which the petition process is to be used, and the operational details of the process are unclear.
Recommendation: NIH should clarify this provision in the following respects: (a) specify whether the petitioning mechanism is limited to human pathogens; (b) allow for the possibility that no biocontainment level will be required in the case of low-risk agents; (c) establish a timeline by which NIH will address the petitions that it receives; and (d) address how IBCs should handle cases in which the organisms in question cannot be identified past the genus level.

▪**Seventh Bullet Point ("Periodically reviewing approved . . ."):** It is unclear whether the "periodic review" specified in this provision is to be carried out in addition to the de novo review.
Recommendation: NIH should clarify if the periodic review is required in addition to the three-year de novo review, and if so, provide additional details on expectations for periodic review, including specification of the protocol sections/elements that require review. Along these lines, is periodic review necessary with a three-year de novo review requirement? If the 3-year de novo review requirement is maintained, NIH should consider the USDA's review

approach, which requires 3-year de novo review, but removed a previous requirement for annual continuing review. [9 CFR §2.31].

▪**Eighth Bullet Point ("Adopting plans which include . . . "):** The Draft Policy is unclear as to whether the IBC must formally adopt any institutional emergency response plans, many of which address areas outside of the IBC's scope.
Recommendation: NIH should clarify whether the IBC must formally adopt all institutional emergency response plans (i.e., in a manner similar to that in which protocols are approved), or whether IBC or BSO review of/consultation regarding the portions of institutional emergency response plans impacting IBC-regulated areas is sufficient.

▪**Tenth Bullet Point ("Reporting certain incidents . . ."):** The first sentence of this section states that reporting is required for incidents that pose a significant risk to human health. However, this modifying phrase is absent in the description of individual incidents that must be reported, thus creating confusion. For example, why would the lack of registration of a human cell line require 24-hour reporting, particularly if a lab were functioning at BSL2? Further, under the fourth sub-bullet point ("Any incidents involving exposures at BSL-2/ABSL-2) . . ."), it is unclear whether minor exposure to an agent not known to cause disease or a non-treatable BSL2 exposure requires reporting. Overall, the lack of clear reporting criteria and thresholds in this section will result in inconsistent reporting practices. For example, a non-biological occupational injury (e.g., back strain) that occurs inside a BSL-3 laboratory could technically be considered a "incident at a BSL-3 facility," but have no biosafety implications. Finally, the term "adventitious agent" (as used in the last sentence of this section) is undefined.
Recommendation: NIH should empower the IBC to determine in its policies and procedures which types of reported incidents require committee-level review, and which can be handled via reporting to and review by the BSO. Further, our organizations urge NIH to explicitly state that incidents are reportable to NIH only when the IBC determines that they are biologic in nature and pose a significant risk to human health, by making the following modifications to this section:

- **First Sentence:** Modify this sentence to read as follows: "Reporting certain incidents to NIH that the IBC has determined are biologic in nature and pose a significant risk to human health using the required reporting template.

- **Third Sentence:** Modify this sentence to read as follows: "This includes the incidents involving the factors listed below when the IBC has determined such incident is biologic in nature and poses a significant risk to human health:"
- **Fourth Sub-Bullet Point:** Clarify whether exposure to an agent not known to cause disease or untreatable exposures at BSL-2/ABSL-2 that the IBC has determined do not pose a significant risk to human health are reportable.

NIH should provide examples that clearly distinguish reportable and non-reportable events to promote consistent interpretation and reporting. Finally, NIH should include a definition for "adventitious agents" in the General Definitions section.

▪**Eleventh Bullet Point ("Reviewing certain lower-risk incidents . . . "):** If NIH intends for this policy to be a risk-based policy and to empower the IBC and BSO to provide appropriate oversight, it is unclear (1) why any incidents at BSL-1/ABSL-1 require mandatory reporting to/review by the IBC, as opposed to being handled via interaction with the BSO, with reporting to the IBC as the BSO determines is appropriate in accordance with institutional/IBC policies and procedures.

Recommendation: NIH should modify this bullet point and its two sub-bullet points to remove any references to BSL-1/ABSL-1 and to instead include the following statement:

> Incidents at BSL-1/ABSL-1 that (a) do not involve recombinant technology; and/or (b) that involve minor spills of low-risk agents that do not breach containment and that are properly cleaned and decontaminated in accordance with institutional policies and procedures, shall be handled by the researcher in conjunction with the BSO. The BSO shall report to the IBC any such incidents that require reporting under applicable institutional and/or IBC policies and procedures.

▪**Twelfth Bullet Point ("Posting all incident reports .. . . "):** This provision is unclear as to whether public posting is required for incidents that are not required to be reported to NIH.

Recommendation: NIH should modify the first sentence of this provision to read as follows: "Posting of all incident reports for those incidents that are required to be reported to NIH on a public-facing webpage on the website of the institution, using the required incident reporting template."

Biological Safety Officer: As written, the Draft Policy increases the BSO's responsibilities without a corresponding increase in authority or recognition of the subject matter expertise necessary to carry out the BSO's duties.
Recommendation: NIH should define the BSO's authority (e.g., authority to stop work conducted under an IBC approved protocol that poses a significant risk to human health), in addition to detailing responsibilities. Alternatively, the Draft Policy should make clear that the institution is empowered to delegate such authorities to the BSO as are necessary to carry out the responsibilities listed in the Draft Policy. Additionally, NIH should detail any minimum qualifications/competencies that it expects the BSO and/or "other official" assigned to take on these responsibilities to possess. Finally, it was noted that NIH eliminated large scale work (i.e., >10 L) as an independent trigger requiring a BSO, and questions were raised by our members as to whether this was an intentional omission.

Section, III-C, Responsibilities of the Principal Investigator: This section should make clear that the PI's responsibilities must be carried out within the framework of IBC and institutional policies and processes.
Recommendation: NIH should modify the first sentence of this section to read as follows: "The responsibilities of the PI include following all institutional and IBC policies and procedures including those governing the following duties:"

Section III-D, Responsibilities of the National Institutes of Health (NIH): The Draft Policy lists NIH responsibilities, but it lacks processes that NIH will follow in carrying out these responsibilities, including applicable timelines. Additionally, this section fails to include clear mechanisms for how NIH will directly communicate with assured institutions and registered IBCs.
Recommendation: NIH should provide details on the processes that it will follow in carrying out its responsibilities under this section, including associated timelines, particularly with respect to when NIH will provide decisions regarding containment levels, Biosafety Assurances, and incident reports. NIH should also include within its listed responsibilities an obligation to directly communicate with all assured institutions and registered IBCs regarding proposed policy changes and interpretations and provide ample time for comments. Additionally, NIH should establish a central webpage where all containment and other IBC-related determinations are posted.

Section IV, Categories of Oversight for Research Based on Risk: See comments below.

Section IV-1, Research that Requires NIH and IBC Approval Before Initiation: This section of the Draft Policy specifies the research and requests that must receive NIH approval, but it fails to provide details regarding the operational process for making these requests or how NIH will conduct its scientific review. Further, this section lacks any information concerning the timeline for decision-making by NIH, as well as any circumstances that warrant expedited decision-making.

Recommendation: NIH should provide templates outlining the information to be provided to the agency in connection with (a) review of research involving emerging/novel/zoonotic agents for which the risk group (RG) classification or minimum containment level is not available in the BMBL; (b) initial requests to lower containment for research involving wild type or genetically modified RG3 or RG4 biological agents; and (c) initial requests to lower containment below BSL-2 for research involving gene drive modified organisms (GDMOs). Additionally, NIH should consider initially spelling out the acronym "GDMO" and providing a definition for this term.

To assist institutions and IBCs in better understanding and preparing for the determination process, NIH should also detail how it will conduct its scientific review process, including a description of who will be involved in the process and their subject matter expertise, along with the objective assessment criteria that will be employed. Additionally, NIH should set forth expected review periods, including circumstances that justify expedited review requests, along with a process for IBCs/institutions to obtain status updates, and an escalation mechanism for when a determination is delayed beyond the stated period. Finally, NIH should also clarify whether an institution may proceed with research under interim containment requirements established by the IBC, pending receipt of the NIH determination.

Section IV-2, Research that Requires IBC Review and Approval Before Initiation: The research category listed under the fourth bullet point – "Research with primary cells that may be contaminated by adventitious agents" – is overly broad and includes research posing low-level risks that do not warrant mandatory review by the full IBC. For example, this category encompasses human primary cells, human tissues, human blood-derived materials, non-human primate tissues, and other primary materials that are routinely handled using universal precautions and/or following institutional exposure control plans/occupational health programs and OHSA requirements related to bloodborne pathogens.

Recommendation: As previously noted, NIH should include a definition for the

term "adventitious agents." Additionally, NIH should limit the scope of this category to primary cells with known or reasonably suspected contamination by adventitious agents that require specialized containment or response measures beyond universal precautions/OSHA bloodborne pathogen requirements. If NIH rejects these recommended limitations, it should, at the very least, allow for delegated review of activities falling within this category that are routinely conducted in accordance with established institutional controls.

Section IV-3, Research that Requires Review and Approval Before Initiation and May be Delegated to an Individual or Subgroup of IBC Members: The Draft Policy (a) omits the category of Exempt Experiments included in Section III-F of the current NIH Guidelines; (b) omits the category of low-risk experiments requiring only notice to the IBC under Section III-E of the NIH Guidelines; and (c) omits any exemption for transgenic rodents housed at ABSL-1. Instead, the Draft Policy requires delegated review for these low-risk activities resulting in a vastly increased IBC workload and unnecessarily hampering research activities without a corresponding increase in safety benefits. Rather than focusing on allocating IBC efforts and resources to higher-risk activities, the Draft Policy directs limited IBC, institutional, and agency resources to the review of research activities that pose so little risk that they would not even fall within the ambit of a truly risk-based policy.
Recommendation: As NIH has stated, a major goal of the Draft Policy is to establish a risk-based regulatory approach. Accordingly, NIH should retain the categories of exempt experiments and experiments requiring only notice to the IBC simultaneously with initiation as described in Sections III-E and III-F of the current NIH Guidelines.

Section V, Risk Assessment and Mitigation for Research Involving Biohazards: As previously noted the Draft Policy appears to inappropriately equate the terms "biohazard" and "biological agent," by requiring a risk assessment for "research involving ***biohazards***," but only providing a definition of the term "***biological agent.***" Additionally, the Draft Policy significantly expands the categories of research that fall within its scope, but it provides limited operational guidance that IBCs and institutions can use to ensure that mandated risk assessments are performed in an objective and consistent manner. The Draft Policy includes factors to consider in risk assessments, but it lacks any decision-making frameworks that IBCs can use when evaluating these risks and developing risk mitigation strategies. Finally, the use of the word "manipulation" in the phrase "Manipulations of the biohazard," is

confusing because manipulation can be used to refer to either changing the characteristics of the agent (which is addressed elsewhere in the policy) or the physical handling of the agent, which is the topic of this section.
Recommendation: As previously noted, NIH should provide a definition of the term "biohazard" that distinguishes it from "biological agent." NIH should also develop and provide additional tools that IBCs can use to promote objective and consistent risk assessments such as frameworks discussing how risks and benefits should be weighed and evaluated, sample containment determination examples, sample risk mitigation plans, case studies, and FAQs. Finally, NIH should replace the word "manipulations" with "handling."

Section V-A, Requirements and Consideration for Risk Assessment of the Characteristics of the Biohazard: No comments.

Section V-B Requirements and Consideration for Risk Assessment for Genetically Modified Biological Agents, Cells, or Organisms: No comments.

Section V-C, Requirements and Considerations for Risk Assessment for Synthetic Biological Agents or Emerging Technologies: No comments.

Section V-D, Requirements and Considerations for Risk Assessment of Manipulations of Biohazards: As previously noted, to avoid confusion, NIH should replace the word "manipulations" in this section with "handling."

Section V-E, Risk Mitigation Strategies and Laboratory Containment: As previously noted, in some cases GDMOs may be more stable than wild-type organisms, and thus it is unclear why the Draft Policy requires a minimum of BSL-2 for all research involving GDMOs.
Recommendation: NIH should delete the minimum BSL-2 containment requirement for GDMOs and empower IBCs to set an appropriate containment level based on the characteristics of the GDMO.

IBC Meeting Minutes Draft Template: The meeting minutes templates is overly detailed and prescriptive and serves only to impede minutes preparation by requiring reiteration in the minutes of details that are already included in other documentation (e.g., standard operating procedures, research protocols). Further, given that the Draft Policy encompasses non-NIH funded research conducted at institutions that receive NIH funding, the Draft Policy inadequately addresses the types of redactions that are appropriate in cases in which an institution's conduct of non-NIH funded research is subject

to confidentiality and non-disclosure obligations. Finally, the required level of detail in the minutes makes it extremely difficult, if not impossible, for institutions to meet the Draft Policy's deadline for having minutes prepared by the next convened IBC meeting, particularly at institutions that have multiple IBCs meeting frequently.

Recommendation: Our organizations urge NIH to withdraw the required template approach, and instead follow the approach to meeting minutes adopted by the Common Rule, and require only that the institution or IBC "prepare and maintain adequate documentation of all [IBC] activities" including "Minutes of [IBC] meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the [IBC]; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution." [*See*, 45 CFR §46.115]. If NIH maintains the template approach, the agency should consider making the following changes to the template and process for keeping minutes:

- **Timing:** Allow for 90 days to prepare meeting minutes.
- **Redaction Principles:** The NIH's redaction standards do not take into account the fact that the Draft Policy encompasses research that NIH does not fund and that is frequently being conducted pursuant to a contract with a private entity that impose confidentiality and non-disclosure obligations on the institutions carrying out the research. These confidentiality and non-disclosure requirements often include proprietary or pre-patent information that is critical for IBC review, but the public disclosure of which has significant financial and legal implications for the sponsor. Our organizations remain concerned that NIH's inclusion of non-NIH funded research within the scope of the Draft Policy is inappropriate and without statutory authority. Should NIH continue with this approach, our organizations urge the agency to recognize within the template that institutions may cite contractual standards governing non-NIH funded research as the basis for redactions made in meeting minutes. To do otherwise would constitute undue interference with an institution's ability to contract with private entities to carry out research, merely because the institution accepts NIH funding on unrelated projects.
- **Incident Review**: It should be sufficient to include within meeting minutes the same level of detail regarding incidents that is required in public posting of those incidents.

Draft Incident Reporting Template: As with the minutes template, the incident reporting template is overly detailed and prescriptive, and requires the disclosure of information that may compromise the privacy of an individual involved in an incident and the security of research activities. Further, the requirement to publicly post such detailed information, including "root cause analysis," serves to discourage incident reporting and goes against efforts to replace a "blame culture" of incident reporting with a "fair and just culture" approach that facilitates and supports self-reporting.

Recommendation: Our organizations recommend that NIH abandon the mandated template (which is not in effect for either IRBs or IACUCs) and permit anonymized aggregated incident reporting. Alternatively, NIH should require institutions to only report on incidents that pose a significant risk to human health by supplying sufficient detail to provide notice of the event and follow-up corrective actions taken. If NIH retains the proposed incident reporting template, the agency should consider making the following changes:

- **Required Reports:** NIH should reference the provisions of Section III-B of the Draft Policy with respect to the incidents that must be reported instead of repeating this information in the template. The repeated information adds confusion, not clarity (e.g., "administrative failure" description is too broad to be helpful). Further, as previously noted, NIH should limit the incidents required to be reported to those that the IBC determines are biologic in nature and pose a significant risk to human health. This point should be made clear in the form instructions and in the section on incident information. NIH should also clarify if the reporting template is only used for reports to NIH, or if it must be used for internal institutional reporting as well.
- **PI's Name and Grant Information:** Remove the requirement for providing the PI's name, particularly if public posting is required. In labs that have only one or two workers, the posting of the PI's name could lead to identification of the person involved in the incident. For the same reason, grant information that can be used to identify the PI also should be removed prior to publication.

Conclusion: Our organizations appreciate the opportunity to provide comments on the Draft Policy. Our member institutions support robust biosafety review and oversight but have expressed concerns that the Draft Policy tilts too far in the direction of requiring numerous and complicated controls for low-risk research. Such an approach does not serve the cause of increased biosafety because it misallocates ever-more limited resources away

from the oversight of higher-risk activities, while unnecessarily burdening the conduct of low-risk activities. Accordingly, NIH should consider recalibrating its approach by modifying the Draft Policy to better enable IBCs and BSOs to provide independent, risk-based review and oversight. The recommendations expressed above will help to foster such an approach.

Finally, our organizations request that prior to the publication of a final policy, NIH will post for comment a revised draft of the policy that includes a summary of the comments it received and its basis for accepting/rejecting those comments.

If you have any questions regarding this transmittal, please feel free to email the following association representatives:

> **AAU:** Lizbet Boroughs, Senior Associate Vice President for Government Relations and Public Policy at lizbet.boroughs@aau.edu
>
> **APLU:** Deborah Altenburg, Vice President for Research Policy & Advocacy at daltenburg@aplu.org.
>
> **COGR:** Kristin West, Director, Research Ethics & Compliance at kwest@cogr.edu.

Sincerely,



Lizbet Boroughs
Senior Vice President for
Government Relations & Public Policy
AAU



Deborah Altenburg
Vice President for Research,
Policy & Advocacy
APLU



Kristin West
Director, Research Ethics & Compliance
COGR

403. Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

I am responding: On behalf of myself

Name: Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Institutional Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 5-My-Edited-NIH-Policy-Comments-1.docx

Description: Commants provided during the First Regional Listening Session

Listening Session 1: NIH Hearing Comments (296 words)

Andrew Maksymowych, Biosafety Officer at the University of Pennsylvania.

These opinions are my own and do not necessarily represent the views of my employer

(1) The designation "Biosafety Modernization Initiative" is presumptuous. The Biosafety profession existed before the *NIH Guidelines* and will exist with or without guidance from the NIH.

(2) Science and technology have evolved, and the Biosafety profession has endeavored to keep pace. Programs do not exist exclusively to support the *NIH Guidelines*.

(3) Biosafety professionals are practicing "risk based" biosafety. It is the *NIH Guidelines* that have been stuck in the past. With that perspective this initiative is overdue and welcome.

(4) 21 Century Biosafety is not currently defined, nor will it be in the future, strictly by the NIH Policy. The OSP acknowledged that other Federal agencies may have different expectations for biosafety, independent from the new NIH Policy.

Step one, must be to define programmatic pillars for this policy:

(5) **Harmonization:** Will new NIH Policy be harmonized with international biosafety standards?

(6) **NIH Policy:** Must not confound the practice of biosafety.

(7) **Institutional Biosafety Committees:** Have evolved to address biosafety risk assessments beyond narrowly addressing NIH guidance. Are there expectations for significant operational changes?

Will the NIH detail expectations regarding IBC status within institutional compliance committee hierarchy, mandating institutional support and provision of adequate resources?

(8) **The Biosafety Profession:** Empowerment for Biosafety Programs from the NIH is welcome. What this may look like remains to be defined and must be coordinated by biosafety professionals.

(9) **Finally:** "Because we are dealing with the federal government" only Leadership is empowered to pursue such interactions. Guard against persistent tendencies for policy activities such as this to be appropriated by leadership. Consider preferentially, input from biosafety profession "boots on the ground".

Thank you!

404. Alliance for mRNA Medicines

I am responding: On behalf of an organization

Name: Sara Singleton

Name of Organization: Alliance for mRNA Medicines

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Management

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): mRNA medicines

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We have concerns about the scope of the policy. See attached letter which explains in more detail our concern about the definition of "genetic modification" as well as our specific suggestions for how to better define this term. In addition, we recommend a more workable oversight pathway for individualized and N-of-few genome-editing therapies.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): no comment

3. Continued utility of Risk Groups: no comment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): no comment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: no comment

6. Other feedback relevant to this resource: no comment

Uploaded File: AMM-comment-letter-on-NIH-Biosafety-policy.pdf

October 16, 2026

Office of Science Policy
National Institutes of Health

Re: Request for Comment on Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Office of Science Policy:

On behalf of the Alliance for mRNA Medicines (AMM), we appreciate the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards (the Draft Policy). AMM supports strong, science-based biosafety oversight. We respectfully request two targeted changes to ensure that the Draft Policy is calibrated to actual risk and does not impede the development of mRNA medicines or individualized genome-editing therapies.

1. Clarify the definition of genetic modification

Concern:

The Draft Policy defines genetic modification to include the introduction of nucleic acid molecules that "can be transcribed or translated." Transcription and translation are normal functions of nucleic acids and, by themselves, do not alter the host cell's genome. As written, this criterion could classify synthetic mRNA and other non-integrating expression constructs—including mRNA vaccines and therapeutics—as genetic modification, even when their sole function is transient protein expression.

This language is also inconsistent with the Draft Policy's focus elsewhere on stable genomic alteration. Without a clear exclusion, a conservative institutional interpretation could bring routine, non-integrating mRNA research within biosafety oversight intended for materially different risks.

Recommendation

We recommend deleting the following criteria from the definition: "Have the potential for one or more cycles of replication in a cell; or Can be transcribed or translated." The replication criterion should likewise be deleted or narrowed to self-replicating or integrating elements, because non-integrating RNA replicons do not alter the host genome.

We further recommend replacing the definition of genetic modification with the following language:

> "Genetic modification: The introduction into cells, organisms, or viruses of nucleic acid molecules that possess biological properties enabling stable, heritable alteration of the genome (e.g., cis elements involved in integration, gene editing reagents, integrating or self-replicating viral elements); or the introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical, or radiological means. Nucleic acids that are transcribed or translated without altering the host genome, including synthetic messenger RNA and non-integrating expression constructs, are not genetic modification for purposes of this Policy, except where the encoded product is intended to produce stable, heritable alteration of the host genome."

The final clause appropriately preserves oversight for constructs encoding genome-editing tools whose intended function is to produce a stable genomic alteration, while keeping ordinary mRNA vaccines and therapeutics outside the definition.

2. Establish a workable oversight pathway for individualized and N-of-few genome-editing therapies

Concern

Section IV-2 of the Draft Policy requires IBC review and approval before clinical research involving deliberate administration of products capable of shedding, replicating, or integrating. The Draft Policy excludes a clinical product administered to one participant under an FDA-regulated individual-patient expanded access IND. That relief is too narrow for individualized and N-of-few genome-editing therapies.

As drafted, a platform protocol treating more than one patient, or a single patient treated under a conventional or platform IND, may require full IBC review before dosing. In addition, a patient-specific construct could require a new review whenever the change affects the biosafety assessment. This review cadence is poorly matched to validated platforms in which the manufacturing and administration process is common and only the targeting or editing sequence varies.

The Draft Policy also requires public posting of IBC meeting minutes. For a bespoke editing therapy, the construct can effectively be the product, so public disclosure should be carefully calibrated to protect confidential and proprietary information while preserving appropriate transparency.

Recommendation

We recommend extending the clinical exemption to individualized and small-cohort therapies delivered under any FDA-authorized IND, including conventional and platform INDs, where patient-specific variation is limited to the targeting or editing sequence within an otherwise validated platform. The Draft Policy should state:

> “Deliberate administration of an individualized or small-cohort clinical product under an FDA-regulated IND, where patient-specific variation is limited to the targeting or editing sequence within an otherwise validated platform, is not research subject to this Policy and does not require separate IBC review for each patient.”

We also recommend allowing an IBC to approve a validated genome-editing platform and its associated containment and biosafety practices through a master approval. Once that approval is in place, administration to additional participants whose constructs differ only in patient-specific targeting or editing sequence, within the approved risk assessment, should proceed upon notification to the IBC rather than through de novo review. The Draft Policy should state:

> “Where an IBC has approved a genome-editing platform and its associated containment and biosafety practices, administration to additional participants that differs only in patient-specific targeting or editing sequence, within the approved risk assessment, may proceed upon notification to the IBC and does not require a new approval.”

Conclusion

AMM does not seek to remove genome editing from oversight. Editor-encoding constructs intended to alter the genome should remain within the appropriate oversight framework. Our concern is that the Draft Policy, as written, imposes greater burdens on individualized and N-of-few therapies than on a one-off expanded access case without a corresponding difference in biosafety risk. A risk-calibrated pathway would preserve safety while helping bring these therapies to patients who cannot wait.

We appreciate NIH’s consideration of these targeted revisions. Thank you for the opportunity to comment on the Draft Policy.

Sincerely,

Clay Alspach
Executive Director
Alliance for mRNA Medicines

405. Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

I am responding: On behalf of myself

Name: Andrew B. Maksymowych, M.S., Ph.D., RBP(ABSA)

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Institutional Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 4-Biosafety-Policy-Comments-to-NIH-OSP-v2-1.docx

Description: Comments regarding omissions or non-addressed aspects of the NIH Draaft Biosafety Policy

Priority requests to NIH OSP Regarding Biosafety Policy Draft

- **<u>Certify Instutional Biosafety Program Compliance with Policy.</u>**

  1. Certification of **compliance** with the new NIH Biosafety Policy, and **confirmation of programmatic structure**, institutional **empowerment of Biosafety Program**, and **leadership position of Biosafety Officer** must become part of the grant application. Similar to animal program section.

- **<u>Define the minimum requirements for an Instutional Biosafety Program.</u>**

  1. Partial quote: '*. . . the National Institutes of Health (NIH) is committed to ensuring that* ***gold-standard science*** *is conducted under* ***gold-standard biosafety conditions****.*"
  A single, egregious oversite is that the requirement for a "Biosafety Officer" defaults to that listed in the current NIH Guidelines. How can an institution empower and run a "**gold-standard biosafety program"** without mandating a program lead that has significant biosafety experience?

  2. Pick a consistent title for the policy that reflects what the NIH wants / needs: Is this a "Biosafety Policy", a "Biosafety & Biosecurity Policy", or a "Policy for work with Biohazards"? Each of the titles will be interpreted differently by institutional leadership.
  This is important because the draft title "***Biosafety Policy for Research Involving Biohazards"*** (Biosafety & Biosecurity Policy?) does not address the fact that biosafety programs include a comprehensive administrative portfolio that includes research safety, compliance, ethics, training, committee review, and approval portfolio.

  3. Define what level of institutional empowerment must be granted to the Biosafety & Biosecurity program. Must both components be supported or is either one, biosafety or biosecurity, adequate to satisfy this policy?
  A biosafety officer or biosafety professional overseeing this gold standard biosafety program must be granted administrative level empowerment equivalent to the "Director of Animal Welfare", Director of Human Research Protections" or the "Institutional Veterinarian". A more appropriate role, to accomplish what the NIH is striving toward, will be Assistant or Associate Vice Provost or Vice President for Biosafety & Biosecurity Programs. Someone at the institutional leadership level, with appropriate biosafety experience, must be empowered to oversee these programs. **This must be mandated by the policy or it won't**

happen. Lack of this empowerment is currently what fails many biosafety programs.

- **Codify the Institutional Biosafety Committee (IBC)**

  1. Define what level of institutional support is adequate to satisfy policy requirements. Must Institutional resources include similar administrative structure for the IBC that is offered to the IRB and/or IACUC? What is the minimum? Office space, administrative support adequate for the number of IBC committees (or sub-committees), Leadership team consisting of Director, Associate Director, Professional staff separate from the biosafety program? For example, the Director of the IBC office has a separate role from Institutional Biosafety Officer, etc.? The Biosafety Officer sits as a voting member only?

- **Fully Embrace Risk-Based Biosafety**

  1. It is stated that this policy intends to encourage and embrace risk-based oversight and reporting. Yet, the only risk criteria incorporated into this first draft are Biological Agent Risk Groups and Biosafety Levels. These criteria are not applicable to all life science research activities or agents proposed for enhanced biosafety oversight. For example, biologics used in clinical trials cannot be defined by a biological agent Risk Group. Biologics are typically risk assessed by Risk Banding. Include/acknowledge this aspect of risk assessment in the updated draft. Alternatively, allow the biosafety professionals overseeing biosafety programs the freedom to perform risk assessment without specifying the risk criteria that must be used, because in biosafety and especially because of rapidly developing life sciences research programs, "it depends". Please let life science research professionals do what they do best, without restriction.

- **Risk-Based Biosafety**

  1. Since Biosafety Oversight mandated by the New NIH Biosafety Policy is supposed to be risk-based, registration, IBC review, and reporting of Biosafety Level 1 (BSL-1) or biologics band 1, materials and research, is a **NO GO**. Please exempt these low-risk materials from the Policy.

406. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 3-NIH-Biosafety-Policy-Comments-2.docx

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public confidence in NIH-supported science. I offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

Topic to Address*: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any

resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.

3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory

rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:
    a. the nature and stability of the genomic modification;
    b. whether the modification is heritable and the potential for transmission through breeding;
    c. effects on animal health, phenotype, host range, susceptibility, or disease;
    d. potential entry into breeding or food-production systems;
    e. potential environmental release or interaction with non-research animal populations;
    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and
    g. applicable federal, state, or other regulatory oversight.
2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.
3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.
4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

  deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the

Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

b. State explicitly that the Policy does not address non-biological hazards.

c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

  Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

  the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate, and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

  Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and

Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

I believe the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, I request that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, I welcome the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. I do not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. I recommend that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice

- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, I recommend a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with my earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*
- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. I recommend that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior

leadership;

2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply

another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.
NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, I kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. I encourage NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE

BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The

Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While I support appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes
6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions

throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as “any incident,” “loss of containment,” “significant problems,” and “minor spills... generally do not need to be reported,” and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report “potential releases involving facility and/or equipment failures even when redundant systems were functioning properly” would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure

in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: I recommend the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and

occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. I support preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

407. Americans for Medical Progress

I am responding: On behalf of an organization

Name: Naomi Charalambakis

Name of Organization: Americans for Medical Progress

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Director of Communications and Science Policy

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): All work involving research with animals

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Americans for Medical Progress (AMP) appreciates the opportunity to provide comments on the National Institutes of Health's (NIH) Draft Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112) and its associated implementation resources.

AMP is a nonprofit organization dedicated to fostering public understanding of the essential role of animal research in advancing human and animal health. We work closely with biomedical research institutions and the broader scientific community to promote responsible research, openness, and the continued availability of the scientific resources needed to advance medical discoveries.

AMP supports NIH's efforts to modernize biosafety oversight and ensure that biomedical research is conducted under appropriate safety standards. Our comments focus on the policy's implications for animal research: the treatment of routine transgenic animal activities, risk-based incident reporting and public disclosure, coordination with existing oversight programs, and protections for research personnel. Overall, we encourage NIH to ensure that expanded oversight and reporting requirements meaningfully improve biosafety without unnecessarily diverting limited institutional resources to administrative activities that add little value to risk assessment or public safety.

Topic 1: Scope of Research Covered by the Policy

AMP recognizes NIH's decision to expand the policy beyond recombinant and synthetic nucleic acid molecules to all biohazards. Because the draft definition of biohazards includes genetically modified cells and organisms other than plants, and because the updated policy contains no exempt categories, the expanded scope would reach routine transgenic animal activities that are currently exempt from the current policy.

Under the current NIH Guidelines, the purchase or transfer of transgenic rodents and the generation of BL1 transgenic rodents through breeding are exempt (Appendices C-VI and C-VII). The updated draft policy instead lists research with transgenic organisms at BSL-1/ABSL-1 among the activities eligible for delegated review under Section IV-3, which requires approval before initiation and periodic re-approval. As drafted, the breeding, purchase, and transfer of BL1 transgenic rodent lines would therefore appear to require review and approval for the first time. Because these activities make up much of the day-to-

day work of transgenic rodent colonies, this change would subject a large volume of routine, low-risk activity to new approval requirements without any corresponding biosafety benefit.
NIH has identified reducing administrative burden for lower-risk research as a central objective of this modernization effort. Requiring new approvals for activities that are exempt today and raise no new biosafety concerns would run counter to that goal and divert Institutional Biosafety Committee (IBC) attention from higher-risk work. AMP recommends that NIH carry forward exemptions equivalent to Appendices C-VI and C-VII in the final policy or, at minimum, state explicitly that these activities do not require review absent a meaningful change in biosafety risk.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Topic 2: Structure of Tiered Oversight, Risk Calibration, Accountability, Transparency, and Administrative Burden
AMP supports NIH's goal of aligning federal and institutional oversight with the level of risk associated with particular research activities. However, we are concerned that the draft's incident reporting and public disclosure provisions for lower-risk animal research are not proportional to the risks involved.
Incident thresholds
Section III-B provides that "any incident involving research subject to the policy with an animal that is housed at BSL-1/ABSL-1 or BSL-2/ABSL-2 (e.g., bite, scratch, escape or improper disposition)" must be reported to and addressed by the IBC, even when it does not meet the threshold for NIH notification. The draft would also require institutions to publicly post every incident report, including those addressed entirely at the institutional level, and to keep them posted for a minimum of five years.
Animal bites, scratches, and escapes occur during routine animal care and do not, on their own, indicate a failure of biosafety practices or an elevated risk to human health. Many involve no exposure to, or release of, the biological agent under study and are already managed through occupational health, veterinary, and Institutional Animal Care and Use Committee (IACUC) processes. Requiring IBC action and public posting for each event would consume staff time for report preparation, committee coordination, and redaction review while adding little to biosafety risk assessment. That burden would fall most heavily on smaller institutions with limited biosafety, administrative, and legal staff.
The draft already applies this reasoning elsewhere. Section III-B states that minor spills of low-risk agents that involve no breach of containment and are properly cleaned up "generally do not need to be reported," and that treatment for adventitious agents does not trigger NIH reporting unless a laboratory-acquired infection results. AMP recommends that NIH apply the same principle to animal incidents: bites, scratches, and escapes at ABSL-1 or ABSL-2 that involve no exposure to or release of the agent under study should be documented through existing institutional procedures rather than requiring IBC action and public posting.
Public disclosure
AMP encourages NIH to distinguish more clearly between incidents that warrant institutional documentation and those that warrant public disclosure. Rather than requiring publication of every incident subject to IBC review, NIH should establish risk-based thresholds for posting. For incidents below that threshold, a periodic summary describing the general nature of incidents, their biosafety significance, and corrective actions taken would support meaningful transparency without unnecessary disclosure of sensitive research and personnel information.
Coordination with IACUCs
The draft states that it seeks to "reinforce consistency with Institutional Review Boards and Institutional Animal Care and Use Committees," but the policy text does not define a role for IACUCs or address how IBC and IACUC responsibilities interact. Institutions already maintain processes for reviewing animal-

related incidents, occupational injuries, veterinary care, and personnel training. AMP recommends that the final policy expressly allow institutions to coordinate IBC and IACUC reviews and rely on shared documentation, rather than maintain parallel reporting and approval processes for the same event.
Personnel security
Transparency requirements must also account for the safety and security of research personnel. The draft incident reporting and IBC meeting minutes templates provide that information widely available from other public sources, including principal investigator names, biological agents, and grant numbers, may not be redacted. While each item may be individually accessible, compiling it alongside details about animal research activities, incidents, and institutional procedures creates a cumulative disclosure that can heighten security risks.
Scientists and staff involved in animal research continue to face harassment, threats, and other security incidents. AMP encourages NIH to recognize these risks explicitly in its redaction guidance and to allow institutions, in consultation with appropriate security personnel, to withhold information when disclosure could create credible risks to individuals, research facilities, or institutional operations, even when some of that information is otherwise publicly available.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Topic 4: Effectiveness of Compliance and Enforcement Mechanisms, Including Biosecurity Challenges
AMP supports NIH's interest in strengthening compliance and promoting public confidence in biomedical research oversight. We recommend a proportionate approach that distinguishes serious biosafety violations from minor incidents that are promptly identified, documented, and addressed through established institutional procedures.
AMP welcomes the proposed National Biosafety Data and Safety Analysis Center and NIH's commitment that voluntary, confidential near-miss reports would not be used for enforcement. Effective biosafety programs depend on a culture in which personnel report minor incidents and near misses promptly and without fear of disproportionate consequences. Mandatory public posting of low-risk, institution-level animal incidents could work against that culture, because personnel may be less willing to report minor events if each report becomes a public record associated with their laboratory for at least five years. Aligning the treatment of low-risk incidents with the non-punitive approach NIH has proposed for near misses would better support the reporting culture NIH seeks to build.
Regarding biosecurity, AMP notes that the security challenges facing animal research institutions extend beyond protecting biological agents to the physical safety of personnel and facilities, as discussed under Topic 2. We encourage NIH to treat personnel and facility security as part of its biosecurity considerations when finalizing disclosure requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Topics 5 and 6: Implementation Resources, Additional Guidance, and Draft Templates
AMP appreciates NIH's development of standardized incident reporting and IBC meeting minutes templates, which may improve consistency across institutions. We encourage NIH to address the following before the templates become mandatory:
• Consistency with Section III-B: Section III-B distinguishes incidents requiring NIH notification from

lower-risk incidents addressed by the IBC. However, the draft “Incident Reporting Template” states that "completed reports must be sent to NIH" and includes a field for the date of submission to NIH, while elsewhere referring to cases "when the report is required to be submitted to NIH." NIH should reconcile these provisions, clarify the documentation requirements for each category, and confirm that incidents below the NIH notification threshold may be maintained in institutional records without federal submission.

• Redaction guidance: Revise the redaction instructions in both templates to permit institutions to withhold information, including otherwise public information, when institutional security personnel determine that its compilation alongside incident details creates a credible risk to individuals or facilities, as discussed under Topic 2.

• Animal research examples: Provide examples of completed templates for common animal research scenarios, such as minor occupational injuries and animal escapes, including incidents already investigated through IACUC or occupational health programs. The incident template includes an "animal bite/scratch" option but no specific category for animal escapes.

• Transgenic animal activities: Clarify how delegated review under Section IV-3 would apply to transgenic animal research, consistent with our recommendation under Topic 1.

We also encourage NIH to engage laboratory animal veterinarians, IACUC administrators, animal care program leadership, and institutional biosafety professionals in developing these resources. Their practical experience will help ensure the final requirements are effective, workable, and consistent with existing animal welfare and oversight obligations.

Conclusion

AMP appreciates NIH's commitment to strengthening biosafety oversight and developing a framework that reflects the evolving nature of biomedical research.

We encourage NIH to ensure that the final policy balances meaningful transparency and accountability with appropriate protections for research personnel, recognizes existing institutional oversight systems, and maintains reporting requirements proportionate to the risks involved.

Uploaded File: AMPResponse_NOT-OD-26-112_10192026.pdf

Description: PDF copy of AMP's Response to NOT-OD-26-112

October 19, 2026

Lyric Jorgenson, PhD
Associate Director for Science Policy
National Institutes of Health

Re: NOT-OD-26-112 - Draft NIH Biosafety Policy for Research Involving Biohazards

Submitted via submission portal and e-mail (SciencePolicy@od.nih.gov)

Dear Dr. Jorgenson,

Americans for Medical Progress (AMP) appreciates the opportunity to provide comments on the National Institutes of Health's (NIH) Draft Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112) and its associated implementation resources.

AMP is a nonprofit organization dedicated to fostering public understanding of the essential role of animal research in advancing human and animal health. We work closely with biomedical research institutions and the broader scientific community to promote responsible research, openness, and the continued availability of the scientific resources needed to advance medical discoveries.

AMP supports NIH's efforts to modernize biosafety oversight and ensure that biomedical research is conducted under appropriate safety standards. Our comments focus on the policy's implications for animal research: the treatment of routine transgenic animal activities, risk-based incident reporting and public disclosure, coordination with existing oversight programs, and protections for research personnel.

Overall, we encourage NIH to ensure that expanded oversight and reporting requirements meaningfully improve biosafety without unnecessarily diverting limited institutional resources to administrative activities that add little value to risk assessment or public safety.

Topic 1: Scope of Research Covered by the Policy

AMP recognizes NIH's decision to expand the policy beyond recombinant and synthetic nucleic acid molecules to all biohazards. Because the draft definition of biohazards includes genetically modified cells and organisms other than plants, and because the updated policy contains no exempt categories, the expanded scope would reach routine transgenic animal activities that are currently exempt from the current policy.

Under the current NIH Guidelines, the purchase or transfer of transgenic rodents and the generation of BL1 transgenic rodents through breeding are exempt (Appendices C-VI and C-VII). The updated draft policy instead lists research with transgenic organisms at BSL-1/ABSL-1 among the activities eligible for delegated review under Section IV-3, which requires approval before initiation and periodic re-approval. As drafted, the breeding, purchase, and transfer of BL1 transgenic rodent lines would therefore appear to require review and approval for the first time. Because these activities make up much of the day-to-day work of transgenic rodent colonies, this change would subject a large volume of routine, low-risk activity to new approval requirements without any corresponding biosafety benefit.

NIH has identified reducing administrative burden for lower-risk research as a central objective of this modernization effort. Requiring new approvals for activities that are exempt today and raise no new biosafety concerns would run counter to that goal and divert Institutional Biosafety Committee (IBC) attention from higher-risk work. AMP recommends that NIH carry forward exemptions equivalent to Appendices C-VI and C-VII in the final policy or, at minimum, state explicitly that these activities do not require review absent a meaningful change in biosafety risk.

Topic 2: Structure of Tiered Oversight, Risk Calibration, Accountability, Transparency, and Administrative Burden

AMP supports NIH's goal of aligning federal and institutional oversight with the level of risk associated with particular research activities. However, we are concerned that the draft's incident reporting and public disclosure provisions for lower-risk animal research are not proportional to the risks involved.

Incident thresholds

Section III-B provides that "any incident involving research subject to the policy with an animal that is housed at BSL-1/ABSL-1 or BSL-2/ABSL-2 (e.g., bite, scratch, escape or improper disposition)" must be reported to and addressed by the IBC, even when it does not meet the threshold for NIH notification. The draft would also require institutions to publicly post every incident report, including those addressed entirely at the institutional level, and to keep them posted for a minimum of five years.

Animal bites, scratches, and escapes occur during routine animal care and do not, on their own, indicate a failure of biosafety practices or an elevated risk to human health. Many involve no exposure to, or release of, the biological agent under study and are already managed through occupational health, veterinary, and Institutional Animal Care and Use Committee (IACUC) processes. Requiring IBC action and public posting for each event would consume staff time for report preparation, committee coordination, and redaction review while adding little to biosafety risk assessment. That burden would fall most heavily on smaller institutions with limited biosafety, administrative, and legal staff.

The draft already applies this reasoning elsewhere. Section III-B states that minor spills of low-risk agents that involve no breach of containment and are properly cleaned up "generally do not need to be reported," and that treatment for adventitious agents does not trigger NIH reporting unless a laboratory-acquired infection results. AMP recommends that NIH apply the same principle to animal incidents: bites, scratches, and escapes at ABSL-1 or ABSL-2 that involve no exposure to or release of the agent under study should be documented through existing institutional procedures rather than requiring IBC action and public posting.

Public disclosure

AMP encourages NIH to distinguish more clearly between incidents that warrant institutional documentation and those that warrant public disclosure. Rather than requiring publication of every incident subject to IBC review, NIH should establish risk-based thresholds for posting. For incidents below that threshold, a periodic summary describing the general nature of incidents, their biosafety significance, and corrective actions taken would support meaningful transparency without unnecessary disclosure of sensitive research and personnel information.

Coordination with IACUCs

The draft states that it seeks to "reinforce consistency with Institutional Review Boards and Institutional Animal Care and Use Committees," but the policy text does not define a role for IACUCs or address how IBC and IACUC responsibilities interact. Institutions already maintain processes for reviewing animal-related incidents,

occupational injuries, veterinary care, and personnel training. AMP recommends that the final policy expressly allow institutions to coordinate IBC and IACUC reviews and rely on shared documentation, rather than maintain parallel reporting and approval processes for the same event.

Personnel security

Transparency requirements must also account for the safety and security of research personnel. The draft incident reporting and IBC meeting minutes templates provide that information widely available from other public sources, including principal investigator names, biological agents, and grant numbers, may not be redacted. While each item may be individually accessible, compiling it alongside details about animal research activities, incidents, and institutional procedures creates a cumulative disclosure that can heighten security risks.

Scientists and staff involved in animal research continue to face harassment, threats, and other security incidents. AMP encourages NIH to recognize these risks explicitly in its redaction guidance and to allow institutions, in consultation with appropriate security personnel, to withhold information when disclosure could create credible risks to individuals, research facilities, or institutional operations, even when some of that information is otherwise publicly available.

Topic 4: Effectiveness of Compliance and Enforcement Mechanisms, Including Biosecurity Challenges

AMP supports NIH's interest in strengthening compliance and promoting public confidence in biomedical research oversight. We recommend a proportionate approach that distinguishes serious biosafety violations from minor incidents that are promptly identified, documented, and addressed through established institutional procedures.

AMP welcomes the proposed National Biosafety Data and Safety Analysis Center and NIH's commitment that voluntary, confidential near-miss reports would not be used for enforcement. Effective biosafety programs depend on a culture in which personnel report minor incidents and near misses promptly and without fear of disproportionate consequences. Mandatory public posting of low-risk, institution-level animal incidents could work against that culture, because personnel may be less willing to report minor events if each report becomes a public record associated with their laboratory for at least five years. Aligning the treatment of low-risk incidents with the non-punitive approach NIH has proposed for near misses would better support the reporting culture NIH seeks to build.

Regarding biosecurity, AMP notes that the security challenges facing animal research institutions extend beyond protecting biological agents to the physical safety of personnel and facilities, as discussed under Topic 2. We encourage NIH to treat personnel and facility security as part of its biosecurity considerations when finalizing disclosure requirements.

Topics 5 and 6: Implementation Resources, Additional Guidance, and Draft Templates

AMP appreciates NIH's development of standardized incident reporting and IBC meeting minutes templates, which may improve consistency across institutions. We encourage NIH to address the following before the templates become mandatory:

- Consistency with Section III-B: Section III-B distinguishes incidents requiring NIH notification from lower-risk incidents addressed by the IBC. However, the draft “Incident Reporting Template” states that "completed reports must be sent to NIH" and includes a field for the date of submission to NIH, while elsewhere referring to cases "when the report is required to be submitted to NIH." NIH should reconcile

these provisions, clarify the documentation requirements for each category, and confirm that incidents below the NIH notification threshold may be maintained in institutional records without federal submission.

- Redaction guidance: Revise the redaction instructions in both templates to permit institutions to withhold information, including otherwise public information, when institutional security personnel determine that its compilation alongside incident details creates a credible risk to individuals or facilities, as discussed under Topic 2.
- Animal research examples: Provide examples of completed templates for common animal research scenarios, such as minor occupational injuries and animal escapes, including incidents already investigated through IACUC or occupational health programs. The incident template includes an "animal bite/scratch" option but no specific category for animal escapes.
- Transgenic animal activities: Clarify how delegated review under Section IV-3 would apply to transgenic animal research, consistent with our recommendation under Topic 1.

We also encourage NIH to engage laboratory animal veterinarians, IACUC administrators, animal care program leadership, and institutional biosafety professionals in developing these resources. Their practical experience will help ensure the final requirements are effective, workable, and consistent with existing animal welfare and oversight obligations.

Conclusion

AMP appreciates NIH's commitment to strengthening biosafety oversight and developing a framework that reflects the evolving nature of biomedical research.

We encourage NIH to ensure that the final policy balances meaningful transparency and accountability with appropriate protections for research personnel, recognizes existing institutional oversight systems, and maintains reporting requirements proportionate to the risks involved.

Thank you for considering these comments and for the opportunity to contribute to this important policy discussion.

Sincerely,



Paula Clifford, MLA, RLATG, CVT
Executive Director
paula@amprogress.org
(202) 624-8812

408. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 2-Feedback-NIH-Comments-2.docx

Comment to NOT-OD-26-112

I appreciate NIH's sustained engagement with the research community and supports the goal of a modern, risk-based biosafety framework that is transparent, adaptive, and accountable. The draft policy makes meaningful progress by expanding attention beyond recombinant and synthetic nucleic acid research, clarifying several incident-reporting thresholds, permitting delegated review for specified lower-risk activities, and recognizing the need for implementation resources.

At the same time, the proposed policy would substantially expand institutional scope, review, documentation, public-posting, assurance, and reporting obligations. In its current form, it does not provide proportionate authority, resources, training infrastructure, or implementation time for institutions, IBCs, and biosafety professionals expected to carry out those responsibilities. The result could be increased administrative burden without a corresponding improvement in risk reduction, particularly for routine low-risk research and for smaller or less-resourced institutions.

Priority Recommendations

Issue	Requested NIH action
Scope and definitions	Define key terms with sufficient precision to support consistent institutional determinations. Specifically, define *biohazard* and revise the definitions of *biological agent*, *toxin*, *genetic modification*, *laboratory*

Issue	Requested NIH action
	research, and *genetically modified organism (GDMO)* to ensure the policy's scope is internally consistent, risk based, and aligned with its intended oversight objectives.
Low-risk research	Allow research institutions the flexibility to regulate low-risk research according to their own risk assessments and processes without mandatory delegated IBC approval.
Federal versus local review	Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow IBCs to rely on published NIH precedents.
IBC and BSO authority	Pair expanded responsibilities with explicit authority, independence, access, escalation, and institutional support.
Transparency	Replace universal public posting of detailed minutes and incident reports with standardized, de-identified public summaries and clear redaction rules.
Incident reporting	Retain clear federal thresholds, clarify overlapping categories, and preserve confidential near-miss reporting and local management of lower-risk events. Allow flexible templates to account for institutional needs.
Implementation	Provide final templates, training, databases, examples, and assurance guidance before implementation; use pilots and a minimum 24-month phased transition.

1. Scope of Research Covered by the Policy

Define the boundary of the policy

The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.

Use internally consistent terminology

The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.

Clarify plant and animal coverage

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk

and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Calibrate toxin and protein scope to meaningful risk

The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and other self-aggregating proteins” in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

“Biomedical research” should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported “in full” at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee’s role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish

exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Risk Assessment and the Continued Utility of Risk Groups

Retain Risk Groups as a starting point

Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.

Distinguish genetic engineering from other forms of change

The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.

Avoid rigid containment rules that conflict with risk assessment

A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Roles, Responsibilities, Compliance, and Transparency

Align accountability with authority

The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.

Provide procedures for managing overlapping federal policies

The draft says research also under another federal agency's regulation or purview "may proceed under

the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.

Assign institutional responsibilities appropriately

The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.

Clarify governance requirements

A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure,"

“compliance violation,” and “minor spill.” The policy should clarify whether precautionary post exposure prophylactic treatment is considered “agent-specific treatment”. It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents.

5. Implementation Resources, Timeline, and Funding

Provide a minimum 24-month phased implementation period

The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.

Pilot the policy and templates

NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.

Develop implementation resources

Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.

Address the cost of compliance

The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures,

workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

Allow flexible institutional models

The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Requested Clarifications and Targeted Revisions

Recommend that NIH address the following items expressly in the final text or in binding implementation guidance:

- Define biohazard and clearly state the policy's treatment of animal-only pathogens, plant pathogens, genetically modified plants, greenhouse research, environmental release, toxins, and disease-associated self-propagating proteins.
- Clarify whether another federal agency's approval substitutes for NIH-policy oversight, satisfies a portion of the NIH requirements, or operates concurrently with IBC review.
- Establish an explicit precedence rule between Sections IV-1, IV-2, and IV-3 and state how de novo renewals are categorized. Create an exempt category section for lower risk agents such as transgenic organisms at BSL1.
- Define when a prior NIH containment determination may be used by another institution without a new petition.
- Specify the institutional authority, independence, and access expected for a BSO or alternate official performing BSO duties.
- Define allowable and required redactions and replace detailed public disclosures with de-identified summaries wherever possible.
- Clarify the review and public-reporting expectations for lower-risk animal incidents, first-aid events, minor spills, and compliance violations that do not present a meaningful safety risk.
- Provide a transition mechanism for Biosafety Assurance approval so ongoing covered research is not halted because NIH review is incomplete on the effective date.

A final policy should be clear in scope, calibrated to meaningful risk, harmonized with other federal requirements, and workable across institutions with widely differing resources. It should empower qualified local expertise, reserve federal preapproval for well-defined high-risk or uncertain circumstances, protect a strong reporting culture, and provide sufficient tools, funding, and transition time for sustainable implementation.

409. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 1-Recommendations-to-the-NIH-OSP-2.docx

I ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

1. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts;

compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

2. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure

implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological

exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

3. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

4. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

5. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

6. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and

explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

7. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions.

Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

410. Cheryl McGraw

I am responding: On behalf of myself

Name: Cheryl McGraw

Name of Organization: Mount Holyoke College

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Failure to include plants which can negatively impact the local environment, not just those with the potential to cause immediate harm to humans, should be included. (non-native species, or modified plants with the potential to alter or replace non-modified local flora) Not all harm is immediate.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Having templates for meeting minutes is beneficial to create uniformity. A great deal still needs to be clarified about level of detail required, and ability to redact. Often detail conflicts with confidentiality of research lines and false alarm can be generated where members of the public reading the document may lack context to understand the research.

The template for incident reporting is far too much for minor incidents. It will create a huge administrative burden for what are essentially the office equivalent of paper cuts. It will likely also result in non-reporting. A separate, much less detailed incident report, or better yet, not requiring a report for minor incidents, is called for.

6. Other feedback relevant to this resource: Please see attached.

Uploaded File: NIH_Biosafety_Changes_Response.docx

Description: Please see attached document for feedback.

Subject: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Personal Commentary and Support for CSHEMA and BSAA Recommendations

To Whom It May Concern:

I am submitting this comment in response to the National Institutes of Health (NIH) effort to modernize and strengthen the oversight of biosafety.

While I support the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA) and the Biosafety Administrators Association (BSAA) regarding this effort, there are a few areas in which I would like to add a bit more emphasis.

Delegated Member Review – thank you for this, it is much needed. However, it makes little sense, and a great deal more expense to institutions, to offer this option then have the same information be reviewed at a full committee meeting. A preferable scenario would be that the proposal goes out to the full committee to read and provide opportunity for any member to request that it be full committee review. Absent anyone requesting FCR, the DMR should be sufficient and not require an additional review during an IBC meeting.

Public posting of minor incidents could have a chilling effect on research in the United States. A cut from a slide, or a scratch from a mouse, especially when students are learning how to handle slides and rodents, are incredibly common and akin to receiving a paper cut while filing. Much of the public is unaware of this fact, and posting minor incidents that involve nothing more than basic first aid could all to easily result in misinterpretation and condemnation. Afraid of the that, people may choose to not report. Or PIs may choose to stop teaching students in their labs, setting up scenarios where students in the US won't have the same experience and opportunities, leaving them less qualified for the job market and graduate school education. There is no justifiable reason for this, especially when records can be kept internally and be made available to NIH upon request. I strongly urge NIH to reconsider the proposal to publicly post minor incidents.

Payment to Community Members. I applaud NIH for strengthening oversight to include toxins, infectious agents, etc., but there will be large scale increase in the amount of work a biosafety committee has as a result. It is difficult enough to find community members willing to give up their time to serve, as it is, but to increase the workload without allowing some form of honorarium or stipend to cover their time and travel expense (gas is expensive!) will make it nearly impossible for IBCs to find and maintain community members. Both IRBs and IACUCs offer honoraria for their community member's service, the IBC should as well.

Both the BSAA's and CSHEMA's comments appropriately reflect the needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

As an individual, my work as Regulatory Compliance Administrator for Research and Education would be directly impacted by a new NIH policy on biosafety and I support the recommendations outlined by both organizations.

Thank you for the opportunity to comment.

Sincerely,

Cheryl McGraw
Regulatory Compliance Administrator for Research and Education
Mount Holyoke College
South Hadley, MA
cmcgraw@mtholyoke.edu

411. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Scope of Research Covered by the Policy
Define the boundary of the policy
The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define “biohazard.” The operative scope instead combines a human-health risk threshold with selected categories of materials. This leaves uncertainty for materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions that require IBCs to assess environmental and population effects. NIH should define “biohazard” and state clearly whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework.
Use internally consistent terminology
The definition of “biological agent” is limited to bacteria, viruses, fungi, or parasites that cause human disease, although the term is used elsewhere in connection with RG1 materials, zoonotic agents, genetically modified agents, and agents of uncertain pathogenicity. CSHEMA recommends a neutral definition of biological agent, with a separate risk-based definition for a biohazardous agent. NIH should also define GDMO consistently and reconcile references to gene drive modified organisms, gene drive modified biological agents, and GDMOs.
Clarify plant and animal coverage
The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another agency satisfies NIH policy obligations and when concurrent IBC review remains required.
Calibrate toxin and protein scope to meaningful risk
The draft appears to cover all toxins and to require delegated review of non-Select Agent toxin proteins without a de minimis quantity, potency, concentration, or activity threshold. It also uses “prions and

other self-aggregating proteins" in ways that could be read more broadly than the disease-associated definition. NIH should distinguish biological toxins from other hazardous proteins; address inactive derivatives, subunits, and nucleic acids encoding toxins; establish risk-based thresholds or exemptions; and limit the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials.

Separate scientific definitions from policy applicability

"Biomedical research" should be defined by the nature and purpose of the activity, not by whether it occurs at an NIH-funded institution. Applicability to non-NIH-funded research at recipient institutions should be addressed separately. Likewise, clinical research involving biohazards should be defined independently rather than forced into a laboratory setting described by BSL or ABSL terminology.

Clarify policy application on existing IBC approvals

NIH must define a process for managing research with existing IBC approvals. For example, organisms without a risk group assignment or biosafety level guidance in the BMBL, but an institutional IBC has assigned containment levels based on risk assessment and literature support.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered Oversight and Calibration to Risk

Create a clear precedence rule

Sections IV-2 and IV-3 overlap. Genetically modified cells, viruses, and organisms appear in the full committee category, while several subsets of the same work appear in the delegated category. The final policy should state expressly that the most specific category controls and should provide a decision table with examples for full committee review, delegated review, registration, exemption, and NIH review.

Ensure delegated review actually streamlines oversight

Delegated review is a welcome modernization, but requiring every approval to be reported "in full" at the next IBC meeting and included in publicly posted minutes may recreate much of the workload the pathway is intended to avoid. Institutions should be permitted to provide a concise approval log or aggregate report to the IBC, with records retained for audit. The full committee's role after delegated approval should also be defined.

Remove mandatory review of routine minimal-risk activities

Commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should not automatically require IBC member review when a documented institutional screening process determines that they present minimal biosafety risk. NIH should establish exemptions or administrative registration pathways and permit institutions to elevate work when local circumstances warrant.

Limit federal review to clearly defined circumstances

Requiring NIH approval whenever an emerging, novel, or zoonotic agent lacks a Risk Group classification or minimum containment recommendation in the BMBL could capture many uncommon agents currently routinely handled at both BL1 and BL2, for example organisms discovered during environmental screens. NIH should define the trigger narrowly, permit qualified IBCs to make interim or final determinations for well-characterized agents, and reserve NIH preapproval for circumstances involving substantial uncertainty or potentially significant public or environmental consequences.

Make NIH precedents reusable

NIH should create a searchable national determination and risk-classification database and define substantial equivalence, permissible deviations, documentation expectations, and who determines

whether a prior decision applies. The draft anticipates publication of approved lower-containment determinations but does not state whether another institution may rely on them.

3. Continued utility of Risk Groups: Risk Assessment and the Continued Utility of Risk Groups
Retain Risk Groups as a starting point
Risk Groups remain useful for hazard communication and initial characterization, but they should not independently dictate containment or review level. The final policy should preserve experiment-specific and site-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations.
Distinguish genetic engineering from other forms of change
The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means. This could bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory oversight without a demonstrated increase in biosafety risk. NIH should distinguish deliberate genetic engineering from selection, adaptation, reassortment, and induced mutagenesis and assign oversight based on the resulting phenotype and risk.
Avoid rigid containment rules that conflict with risk assessment
A universal minimum of BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow equivalent risk-based containment and provide technology-specific guidance. Influenza language should also specify which segments, proportions, phenotypes, and virus types trigger BSL-3 enhanced containment rather than using language that could apply to any construct containing any listed segment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Roles, Responsibilities, Compliance, and Transparency
Align accountability with authority
The policy expands BSO and IBC responsibilities without defining corresponding authority. BSOs and IBCs should have explicit access to facilities and relevant records, direct reporting and escalation pathways, authority to require corrective measures, and authority to stop or suspend unsafe work when necessary.
Provide procedures for managing overlapping federal policies
The draft says research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" after approvals or clearances are obtained. This conflicts with the later statement that clinical research cannot begin until IBC and all other institutional and regulatory approvals are obtained, which clearly contemplates cumulative oversight. The final policy should explain when oversight by another agency satisfies NIH policy obligations and when concurrent IBC review remains required.
Assign institutional responsibilities appropriately
The PI can ensure proper use of equipment and report deficiencies, but may not control building ventilation, certification contracts, capital repairs, emergency power, or central maintenance. The final policy should allocate responsibility among the institution, program leadership, facilities owner, BSO, PI, and equipment user. Occupational health requirements should likewise include clear triggers, assigned authorities, and responsibility for developing and communicating required procedures.
Clarify governance requirements
A member who is recused because of a conflict should not count toward the quorum needed for action on that matter. NIH should specify the quorum and voting denominator after recusal, as well as expectations for remote participation, use of ad hoc consultants, and reasonable approaches for

institutions that have difficulty recruiting unaffiliated members.

Recalibrate public posting

Public posting of detailed IBC minutes and all incident reports could expose proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, where identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.

Define redaction and timing rules

If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. The NIH must also establish a defined endpoint for NIH's "final response." Institutions should not be held to a posting deadline that depends on an open-ended federal review.

Map retention requirements to record types

The final policy should include a record-retention table for protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. The table should identify the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident Reporting and Safety Learning

Preserve the clearer federal reporting thresholds

CSHEMA supports the draft's effort to identify specific categories for immediate notification and follow-up reporting. Clear thresholds and examples can improve consistency and allow NIH to focus on events with potential public health or community significance.

Resolve overlapping and undefined categories

The draft should define "incident," "basic first aid," "agent-specific treatment," "potential exposure," "compliance violation," and "minor spill." The policy should clarify whether precautionary post exposure prophylactic treatment is considered "agent-specific treatment". It should clarify whether any event at BSL-3 or BSL-4 is reportable regardless of relevance to biohazard containment and distinguish administrative noncompliance from events presenting an actual biosafety risk. Administrative noncompliance and low risk items should not necessitate a 24-hour reporting timeframe.

Keep reporting of lower-risk events within local IBC purview

NIH should not require every internally reviewed minor event to be publicly posted with unredacted identifying information. Institutions should retain authority to manage lower-risk events and near misses through local IBC review systems.

Use aggregate public reporting

The information required for public posting of incident reports may inadvertently provide enough information to identify the individual(s) involved, potentially resulting in unintentionally violating federal rules about disclosure of medical information. To address this and the issues listed above related to public posting, NIH should develop a confidential, de-identified national reporting system that can support trend analysis and shared learning. This system is only useful if its boundaries are clear and if both institutions and researchers trust that voluntary submissions will not be used for enforcement. NIH

should publish annual de-identified summaries, trends, contributing factors, and lessons learned. This approach would improve transparency and safety learning without attaching names or institutions to routine, well-managed incidents

6. Other feedback relevant to this resource: Implementation Resources, Timeline, and Funding
Provide a minimum 24-month phased implementation period
The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.
Pilot the policy and templates
NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory. 6
CSHEMA | Public Comment
Develop implementation resources
Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.
Address the cost of compliance
The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.
Allow flexible institutional models
The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

Uploaded File: ABSA-NIH-Biosafety-Policy-Comments-Final-15Oct2026.pdf

Description: Comments from ABSA

ABSA International — The Association for Biosafety and Biosecurity

Organization:	ABSA International 1200 Allanson Road, Mundelein, IL 60060 Phone: (866) 425-1365 | Email: info@absa.org | Web: www.absa.org
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To:	Office of Science Policy National Institutes of Health 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892
Submission Portal:	Submitted via NIH OSP Electronic Comment Portal
Subject / Notice:	Formal Public Comments and Recommendations on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice Number: NOT-OD-26-112)

ABSA International, the Association for Biosafety and Biosecurity, is a nonprofit professional association representing biosafety and biosecurity professionals in the United States and internationally. Our membership spans academic and research institutions, government laboratories, biotechnology companies, healthcare organizations, public health agencies, and consulting practices. Members bring scientific, technical, operational, and regulatory expertise across diverse biological research and laboratory settings.

ABSA's comments reflect the practical experience of professionals responsible for translating biosafety policy into daily practice. Our members conduct risk assessments, support Institutional Biosafety Committees (IBCs), develop training and containment practices, investigate incidents, and advise institutions on compliance. They understand how policy requirements affect laboratory safety, reporting culture, institutional resources, and the conduct of research.

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public

confidence in NIH-supported science. ABSA supports NIH's efforts to strengthen biosafety oversight. We offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

***Topic to Address**: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:

    a. the nature and stability of the genomic modification;

    b. whether the modification is heritable and the potential for transmission through breeding;

    c. effects on animal health, phenotype, host range, susceptibility, or disease;

    d. potential entry into breeding or food-production systems;

    e. potential environmental release or interaction with non-research animal populations;

    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and

    g. applicable federal, state, or other regulatory oversight.

2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

    Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

ABSA International believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, ABSA International requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, ABSA International welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. ABSA International does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. ABSA International recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, ABSA International recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with ABSA's earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. ABSA International recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, ABSA International kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. ABSA International encourages NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While ABSA supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: ABSA recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

412. Robyn Roberts

I am responding: On behalf of myself

Name: Robyn Roberts

Name of Organization:

Type of Organization: Not Applicable

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): plant pathology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The "One Health" initiative highlights the importance of including all scientific and environmentally-related disciplines to promote human health. It is a major oversight to remove plants from the biosafety protocol. Limiting biosafety guidelines to agents that directly risk "human health" ignores important biological threats to agriculture and the researcher. Specifically:

1. There are many plant pathogens that produce toxins or other agents that adversely affect humans, such as mycotoxins. Examples include aflatoxins produced by Aspergillus species, and deoxynivalenol (DON) produced by Fusarium species, both of which are highly toxic to humans and animals.

2. Releasing genetically modified plants into the environment could result in cross-pollination with agricultural crops or native species, potentially impacting the health of consumers (people, animals), or cause environmental impacts. For example, it could result in population shifts in food sources for pollinators required for agricultural production, and changes in food availability to predators that look toward livestock as secondary food sources.

3. Unintentional release or introduction of pathogens and pests has resulted in many agriculturally significant epidemics that caused food scarcity and/or famine. For example, the Irish Famine (Phytophthora infesans), wheat stem rust (Puccinia graminis), and rice blast (Magnaporthe oryzae).

4. Plant viruses can be easily cloned and introduced to crops. Viruses are a significant threat to agriculture due to the bioterrorism potential, and can be derived completely synthetically. Under the drafted guidelines, a person could order a synthetic virus with gain-of-function potential and accidentally release it through person-to-plant contamination without the proper biosafety guardrails.

5. There are many plant pathogens that are opportunistic human pathogens. All work with pathogens should be evaluated alongside researchers to determine risk of opportunistic infection.

6. It is unclear if plant-hosted insects are included in the “plants” exception. There are many agricultural pests that could cause significant damage to US agriculture, and there are many examples of insects that have been introduced which cause severe agricultural impacts. These include Rocky Mountain Locust (Melanoplus spretus), Boll Weevil (Anthonomus grandis), and the Japanese Beetle (Popillia japonica).

Additionally, the scope of the policy is unclear. The statement that the policy covers “all biomedical research, in laboratory settings, involving biohazards” seems to limit its application to laboratory-based activities. It is unclear whether the policy also applies to field, greenhouse, animal facilities, environmental studies, and other non-laboratory activities involving biological hazards.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): It is unclear what are the definitions of “incident,” “compliance violation,” and “failure to maintain IBC approval.” For example, it is unclear if reporting would be required at any biosafety level for spills remaining within primary containment, a minor event with no exposure or environmental release, or a needlestick involving a sterile needle. Additionally, it is unclear whether “within 24 hours” means clock hours, business hours, or the next business day; whether the incident template is required for events not reportable to NIH; whether required incident information may result in enforcement or funding action. The applicable timelines for institutional posting and NIH responses are also unclear.

3. Continued utility of Risk Groups: Clarification is needed on how institutions should determine risk groups and biosafety levels. The draft does not define risk groups, nor does it have a comprehensive risk-group list like the one that currently exists in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). The Biosafety in Microbiological and Biomedical Laboratories 6th Edition focuses primarily on biosafety levels and emphasizes project-specific risk assessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The public posting of incident reports, meeting minutes, and NIH responses raises significant privacy, liability, and operational concerns. Detailed reports may allow individuals or laboratories to be identified, especially when combined with information from journal articles and on institutional and government websites. Public disclosure of select-agent activities, high-containment work, principal investigators, and containment failures may also create physical and personnel security risks.

The policy’s public reporting requirement will likely discourage individuals from reporting incidents, potential exposures, and other safety concerns due to concerns about health privacy, retaliation, reputational harm, litigation, or funding consequences. This is the exact opposite of NIH’s intent. Even the best safety cultures will be negatively impacted by this requirement. Incidents reported to the NIH Office of Science Policy will be included in a newly created anonymized database. This effort in and of itself will significantly increase the transparency of biological incidents while encouraging a strong biosafety culture without fear.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The public posting of incident reports, meeting minutes, and NIH responses raises significant privacy, liability, and operational concerns. Detailed reports may allow individuals or laboratories to be identified, especially when combined with information from journal articles and on institutional and government websites. Public

disclosure of select-agent activities, high-containment work, principal investigators, and containment failures may also create physical and personnel security risks.

The policy's public reporting requirement will likely discourage individuals from reporting incidents, potential exposures, and other safety concerns due to concerns about health privacy, retaliation, reputational harm, litigation, or funding consequences. This is the exact opposite of NIH's intent. Even the best safety cultures will be negatively impacted by this requirement. Incidents reported to the NIH Office of Science Policy will be included in a newly created anonymized database. This effort in and of itself will significantly increase the transparency of biological incidents while encouraging a strong biosafety culture without fear.

6. Other feedback relevant to this resource: I am concerned that the best and brightest American scientists, who received their training in the US and have positively impacted human health, will start leaving the US to work in countries that provide better support, clarity, and guidance to researchers while streamlining the process to safely conduct biohazardous work. This will make the US overall less competitive in science innovation compared to other countries, posing a significant risk to national security, technology and intellectual property, and overall influence around the world.

413. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attachment

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attachment

3. Continued utility of Risk Groups: See attachment

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attachment

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attachment

6. Other feedback relevant to this resource: See attachment

Uploaded File: NIH-Comment-1.pdf

Description: PDF of my comment

Action Items:

1. Create new exemption categories for low-risk research, or, at a minimum, keep current exemptions in place for transgenic animals and certain categories of research. BSL1 and ABSL1 work should have exemption categories if the goal of this policy is to reduce red tape. As written, the red tape actually increases.
2. Change reporting requirements for things that require NIH reports. Low-risk incidents and non-consequential reporting of events would create a safety culture that is counterproductive towards the goal.
3. Add redactions to public facing reports: names, grant numbers, and other identifying information would create unsafe work environments for researchers as well as potentially create conflicts with other privacy laws.
4. Tighten up definitions and scope throughout the policy. Biological agents that cause human disease are the basis for the document, but this is contradicted many times throughout with oversight of BSL1/ABSL1 work.
5. Create a work process where other agency documents and regulations can be used in congruence with or instead of this. This becomes apparent when removing plants specifically but then talking about chemical and radiological mutagenesis.
6. The toxin regulations need to be buttoned up, and the definition shrunk to make the scope more applicable to current risks and foundations of biosafety.
7. There needs to be another draft of this policy for public comment after this first comment period. There are too many things that need clarification that the fear is the final policy after this round of comments may still be unclear and create confusion with implementation.
8. Clear implementation guidance of this policy should be created with concrete examples for many of the agents and functions within.
9. A 6-month implementation timeline is unfeasible, especially at scale and current scope (no exemptions). This would create a burden now, and every 3 years upon protocol renewal.
10. Work with organizations such as CSHEMA and ABSA to refine this policy and open up a new comment period.

This list is not exhaustive. This is a start for the narrative below. These steps, at a minimum, would be needed to feasibly implement anything like this at scale at a large research institution.

A new NIH Policy for Research Involving Biohazards is a welcomed refresh to the NIH Guidelines from over 50 years ago, however, the stated goals of "ensuring that gold-standard science is conducted under gold-standard biosafety" and "removing red tape for low-risk research" seems to be lost in the details of the draft.

The new policy states that its scope will include research involving biological agents, which is defined in the draft as agents that can "cause human disease". The policy goes on to contradict this fact by including review of things that were previously exempt, as well as agents that are worked with at BSL1/ABSL1. I am not sure how this policy can state that it is removing red tape while requiring registration and review of low-risk agents that were previously exempt, as well as stating that the goal is to prevent human disease, when the very definition of BSL1 is that the agents are not disease causing in humans. The mechanism of delegated review is a welcomed process to the IBC; however, this cannot overshadow the fact of the administrative and review burden requiring these "zero risk" activities be approved by the IBC before commencing of work. Along these lines, the reporting requirement to the NIH of a low-risk activity being done without IBC approval leads to an enforcement type atmosphere, rather than a collaborative one, which would be a severe burden on our system.

Additionally, the reporting requirements of this policy will introduce yet another large administrative burden, while actually instilling a culture of non-reporting coming out of the labs. If each incident of zero risk bites/scratches and incidents must be reported to the IBC and then, subsequently, posted on a public facing site, this will cause PIs and labs to not report incidents. This is detrimental to the fundamental way safety should work, as low risk and consequence incidents help inform how processes and procedures work going forward. With the seemingly punitive nature of the new reporting process, many things will not be captured appropriately, and lead to less safety and compliance in the lab. Including PI names, grants, etc will lead to a punitive environment which will lead to less incident reporting. This also has some privacy concerns within the community.

With these reporting requirements, biosafety now feels more like a punitive role, rather than one that strives to help the community with their research. Safety culture is an important part of any organization, especially ours, and with these reporting requirements, this cannot be achieved. PIs will fear to ask for help on any procedures when they think they may be reported to the NIH for any minor "infraction", and incidents will not be reported so that new SOPs can be further developed. Right now, when we walk into a lab space, we are a collaborative group that helps the lab with their projects, but this would lead to them not wanting us in their labs and shutting us out further due to fear and repercussion.

The NIH Policy states that it does not want to interfere with regulations by other entities, so it removes plants from the oversight. However, this is in direct contradiction to itself when it then covers radiological and chemical mutagenesis. These activities are governed under various regulatory and review entities and should not be specifically included in this policy. Toxins are also defined very broadly, as well as confusingly, which leads to contradiction. Toxins are generally chemicals and treated like chemicals when it comes to how they are handled, and therefore the definition should be tightened up to agree with the stated goals of the policy. There are many resources available for toxins, and, if human health is the concern of this policy, information and cutoffs for things like LD50 would be a great place to start when considering toxin safety. Overall, the definition of these remains vague and unhelpful within the policy.

The number of protocols that would come out of the policy being finalized as written is unfeasible to many institutions. Just from the regulation requiring 3 year registrations (we currently are at 5 years) would be a 67% increase in renewal registrations. Also, the zero/low risk protocol number would be unwieldy, if not impossible to review, especially considering a 6-month turnaround with the final policy. Adding the burden of previously exempt and non-human disease-causing materials would be inappropriate and, again, in direct contradiction of the stated goal of the policy.

In conclusion, this policy's aim at reducing red tape and supporting gold standard biosafety misses the mark. The stated goals would be a welcomed change, but the execution of the policy, as written, would fall outside of that end. I believe, minimally, the scope of this policy should be changed where BSL1 and ABSL1 protocols should not need registration, as well as incidents should NOT be posted on a public website. A change in the draft policy would enable institutions to direct their attention and resources to protocols and projects that do have meaningful risk.

Professional associations such as CSHEMA and ABSA have created in depth comments that address many of these high-level comments from above. These organizations should be consulted to revise this draft in detail, and then the community be provided with this draft for additional comment. If gold standard science supported by gold standard biosafety is the goal, working with the community is the only way this can be achieved, and currently, the new policy does not read as that.

414. Institutional Biosafety Committee, UTMB

I am responding: On behalf of an organization

Name: Faith Blum

Name of Organization: Institutional Biosafety Committee, UTMB

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

415. Lisa Young

I am responding: On behalf of myself

Name: Lisa Young

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Research Compliance Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of the policy seems to now cover previously exempt research, such as work with transgenic mice and low risk in vitro work with commonly used cell lines. It should be clarified whether research like this is now subject to review.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comment-on-Biosafety-RFI-.docx

I support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards.

We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information,

and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member

may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

Policy source

Draft NIH Biosafety Policy for Research Involving Biohazards, NIH Notice NOT-OD-26-112, released August 19, 2026. Section references throughout refer to this draft.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

416. Rika Welsh

I am responding: On behalf of myself

Name: Rika Welsh

Name of Organization:

Type of Organization: Other

Type of Organization - Other: concerned citizen

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The unification of oversight for all research involving biohazards, whether or not such research involves recombinant or synthetic nucleic acid technology, is a positive change and one that supports a more comprehensive and cohesive institutional biosafety program. The addition of a Delegated Review mechanism is another positive change, which reduces the burden on IBCs, while providing institutions with the flexibility to define the Delegated Review process in a way that ensures appropriate oversight of lower-risk activities at individual institutions. We support these notable policy improvements.
While many aspects of the draft Policy represent improvements, there are several changes that are likely to have significant negative consequences, as well as points that would benefit from clarification. We respectfully submit the comments below for consideration to further improve the Policy.
• New incident reporting requirements have an expanded scope of what counts as an incident in addition to the requirement to post all incident reports on a public website.
• Impact: These changes are expected to have a significant negative impact. The trust that biosafety programs have built up over the years in supporting researchers and encouraging people to report accidents will be eroded by fear of negative ramifications and/or retaliatory action. Even if reporting is anonymized and only a PI or supervisor name is included in the published report, there is a perceived risk of that information being used against the person, lab, and/or institution. People will be less likely to report accidents, which increases the risks associated with untreated injuries or exposures to hazardous materials.
• Recommendation 1: Individual incident reports should not be publicly posted. Reporting should be to NIH, where data on incidents can be aggregated and trends analyzed and/or reported in a way that removes institutional affiliation to further anonymize individuals involved in an incident. That allows for analysis of the data and identification of trends, which would be a valuable resource to the community, while avoiding negative consequences on the individual, lab, or institution, which would, in turn, undermine the value of the incident reporting process.
• Recommendation 2: If institutions must be required to publicly post incident information, allow an aggregated annual report. Such an approach could be modeled after OSHA's Form 300A (Summary of

Work-Related Injuries and Illnesses). We would strongly recommend this approach for incidents defined by this Policy, which would not be reported to NIH but would be reported to the IBC.
• The draft Policy states that IBC approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required. It further lists failure to maintain IBC approval as a reportable incident.
• Impact: The expected impacts of these changes are a significantly increased administrative burden and unintentional non-compliance. In the absence of a specified term limit, many institutions adopted internal policies that require IBC approval to be renewed within a 5-year period, which also coincides with the length of many grants supporting the approved research activities. Switching to a shorter 3-year renewal cycle presents a significant increase in committee workload. Additionally, well-intentioned PIs may face unexpected emergencies, or their registration renewal may come at a time when they are burdened with high workloads from teaching and/or other institutional responsibilities. Because there is no mechanism described in the draft Policy for allowing extensions to PIs facing extenuating circumstances, failure to renew an IBC registration on time would result in a reportable incident of non-compliance.
• Recommendation 1: Keep a defined term limit on IBC approval but increase the term of IBC approval to 5 years.
• Recommendation 2: Empower IBCs to exercise judgement and flexibility in granting reasonable, one-time extensions to PIs facing extenuating circumstances and/or moving a registration renewal to a different time of year so as not to conflict with other high-workload periods.
• The draft Policy states that research with primary cells that may be contaminated by adventitious agents requires IBC review and approval under Section IV-2. We interpret this new scope to mean that any primary human cell line, tissue, or clinical specimen with an unknown status (has not been tested for bloodborne pathogens or other infectious agents) will have to go to the IBC for approval, whereas none of this material required IBC review previously. Instead, this material fell under the OSHA Bloodborne Pathogens Standard, which requires institutions to establish oversight mechanisms that have worked for many decades.
• Impact: This change is expected to have a significant negative impact. The increased burden on most IBCs will be enormous, with no apparent benefit, since the existing mechanisms to comply with the OSHA Bloodborne Pathogens Standard must still be maintained. This is an unnecessary duplication of oversight, and the increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.
• Recommendation: Allow this type of material to be approved via the new Delegated Review process described in Section IV-3 rather than requiring IBC review. That would allow institutions flexibility to integrate existing biosafety oversight mechanisms into the Delegated Review process defined by the new Policy.
• The draft Policy states that research involving genetically modified cells, viruses, or organisms, other than plants requires IBC approval and approval under Section IV-2. Previously, a large portion of genetically modified cell lines were considered exempt under Section III-F-8, Appendix C-I. For many IBCs, that type of material made up the majority of genetically modified material, and because it was considered exempt and did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely and in accordance with the OSHA Bloodborne Pathogens Standard. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under

Section III-F-8, Appendix C-I now falls under Section IV-2 and requires full committee review.
• Impact: This change is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because the main risk associated with material that fell under Section III-F-8, Appendix C-I was the risk of adventitious agents or bloodborne pathogens, as mentioned in point 3 above. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.
• Recommendation: Retain the Section III-F-8, Appendix C-I exemption, or allow materials that would have fallen under Section III-F-8, Appendix C-I to be approved via the Delegated Review process described in Section IV-3.
• The draft Policy's definition of a genetic modification includes introduction into cells, organisms, or viruses of stable alterations into the genome by passaging. It is not clear what passaging activity falls within the Policy scope. Simply culturing an organism in vitro will lead to accumulation of undefined genetic alterations and could be considered passaging. Cultures that are maintained in a lab are also considered to be passaged through the process of sub-culturing to create multiple stocks from an original sample. Further, most of the time, growing an organism in vitro or in a model system selects for mutations that optimize growth in a lab environment, not in a human host, and these lab-adapted strains typically lose virulence or pathogenicity. The Influenza A/Puerto Rico/8/1934 (H1N1) strain (often called PR8 influenza) is a classic, mouse-adapted laboratory strain of the influenza A virus isolated from a human patient in Puerto Rico in 1934. It is an example of a strain that is a lower risk option for studying influenza. These examples of passaging generally have not required IBC review. In the draft Policy, all of these activities would require IBC review and approval under Section IV-2 (see also point 4 above).
• Impact: The current definition of genetic modification is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because most passaging does not increase the risk of the agent or associated research activities. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.
• Recommendation: We recommend refining the scope of the definition of genetic modifications by defining passaging as the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile. Examples of passaging activities that should be included in Section IV-2 include passaging with the intent or likelihood for an agent to acquire a new virulence trait or antibiotic resistance or to adapt a pathogen to a new host species and/or tissue tropism.
• In the draft Policy, the definition of genetic modification that falls within the scope of the policy now includes modification via chemical or radiological means. Further, the draft Policy requires the IBC to review all genetically modified cells under Section IV-2 (see also point 4 above). The main risk associated with use of chemical or radiological agents to create mutations is in the handling of the chemical or radiological material, not necessarily in handling the cells once the mutagen has been removed. There are separate regulations that apply to chemical and radiological hazards. The use of chemical and radiological hazards is best handled by the respective safety experts who are familiar with the appropriate regulations and safety requirements, not the IBC. Assessment of the risks of these mutagens are outside of the scope of an IBC, since IBC members typically have little to no expertise on chemical or radiological hazards.
• Impact: This is a vast expansion of scope that will duplicate oversight and increase burden on IBCs, without a clear benefit. Further, the IBCs typically lack appropriate expertise for evaluating the risks associated with these mutagens. The increased burden on IBCs will detract attention from higher-risk

matters, which do fall within the expertise of the committee.
• Recommendation: Remove chemical and radiological means from the definition of genetic modifications that fall within the scope of the policy and defer oversight to existing regulations that apply to the use of chemical and radiological hazards. Alternatively, refine the scope to apply to experiments in which the mutagenic agent is combined with the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile, as recommended for passaging in point 5 above.
• The draft policy states that research with genetically modified RG1 biological agents requires Delegated Review under Section IV-3. Previously, most standard cloning and/or protein expression with E. coli and other model host-vector systems were considered exempt under Section III-F-8, and it did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely with proper waste disposal procedures. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8 now requires Delegated Review.
• Impact: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. The increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.
• Recommendation 1: We strongly recommend retaining existing III-F-1 through III-F-8 exemptions.
• Recommendation 2: Furthermore, and supported by decades of safe research experience, we also recommend expanding the exemptions to include other low-risk cloning and protein expression research in model organisms such as E. coli BL21 strains, C. elegans, and Drosophila.
• The draft Policy states that research conducted with transgenic organisms at BSL-1/ABSL-1" requires Delegated Review. Previously, almost all breeding or purchasing of transgenic rodents was exempt under Section III-F-8, Appendix C-VII and was not typically registered with an IBC at all. Instead, oversight of those transgenic rodents typically has been handled through federally mandated Institutional Animal Care and Use Committees (IACUCs) that have biosafety professionals as members who conduct risk assessments and suggest risk mitigation measures as part of that review process. Many IBCs do not even have a mechanism for tracking this information. Additionally, many researchers using transgenic mice are not using any other sort of biological material; the research is often focused on behavioral studies or pre-clinical studies that fall outside the scope of an IBC. A very large proportion of transgenic animal work is done with transgenic rodents and zebrafish, and almost all of that work poses no new risk compared to the unmodified rodents and zebrafish.
• Impact: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. Again, the increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.
• Recommendation 1: We strongly recommend retaining the III-F-8, Appendix C-VII exemption and allow existing oversight of these low-risk animals to continue via the IACUC.
• Recommendation 2: As mentioned in point 7 above, we also recommend expanding the exemptions to include other low-risk transgenic model organisms such as zebrafish, C. elegans and Drosophila.
• The draft Policy defines biological agents that fall within the scope as bacteria, viruses, fungi, or parasites that cause human disease. This definition seems to contradict the draft Policy's requirement for Delegated Review of research with genetically modified RG1 biological agents (see point 7 above). Risk Group 1 agents are not associated with disease in healthy adult humans. Some agents may be considered opportunistic pathogens, but there is currently no list of RG1 organisms that are considered

opportunistic pathogens.
• Recommendation 1: NIH should clarify the nature of biological agents that fall within the scope of the Policy. We recommend that the Policy scope is limited to pathogenic biological agents that cause disease in humans, including opportunistic pathogens but excluding non-pathogenic agents.
• Recommendation 2: As there is no list of RG1 agents, and the list of RG2 agents is incomplete, we further recommend empowering the IBCs, Biosafety programs, and PIs to make the determination of RG1 and RG2 for biological agents that are not currently listed in Appendix B of the NIH Guidelines or the BMBL using the risk assessment guidance provided therein.
• The draft Policy's definition of a genetic modification includes introduction of materials that can be transcribed or translated. This would include materials such as purified or synthetic miRNAs, snRNAs, shRNAs, and mRNAs, which are transient in nature and may lead to changes in gene expression but do not replicate and do not modify or integrate into the genome. Work with such materials was previously exempted under III-F-1 but would now fall under Section IV-2 and require IBC review and approval.
• Impact: The current definition of genetic modification is expected to have a significant negative impact. This will create a significant new burden on IBCs, with no apparent benefit given that no genetic modifications are made with these materials. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.
• Recommendation: We recommend retaining the III-F-1 exemption and removing these materials from the scope of the Policy.
• The scope of the draft Policy includes prions and self-aggregating proteins, and research activities involving these materials would require IBC review and approval. We support the draft Policy as it pertains to prions, but request refinement of the oversight pertaining to self-aggregating proteins. IBC oversight should not extend automatically to every protein capable of self-aggregation. Protein aggregation is common in biology and, by itself, does not establish an infectious or exposure hazard. Oversight should instead focus on proteins or protein assemblies for which there is credible evidence that an aggregated conformer can act as a persistent, self-propagating seed; induce conformational conversion of the corresponding native protein; spread between cells or tissues; and transmit pathology following experimental exposure or inoculation. We recommend the following risk-assessment approach, which is consistent with the BMBL principle that containment decisions should be protocol-driven rather than based only on an agent's name.
• Recommendation 1: Classical mammalian prions and prion-containing tissues should remain categorically within IBC purview because of their established infectivity, potential for serious disease, environmental persistence, and resistance to conventional inactivation procedures.
• Recommendation 2: Seed-competent aggregates of α-synuclein, including preformed fibrils, amplified seeds, and α-synuclein-containing material derived from affected human or animal tissue, should also be subject to IBC review because α-synuclein assemblies have demonstrated prion-like templating, cellular and anatomical propagation, and experimental transmissibility in animal models. Inclusion under IBC oversight should not be understood to mean that α-synuclein is known to be naturally communicable between people or that it presents the same level of hazard as a classical prion.
• Recommendation 3: Other self-aggregating proteins should be evaluated individually rather than be included in Section IV-2 of the draft Policy solely because they form oligomers, fibrils, or amyloid. Relevant considerations should include evidence of experimentally transmissible pathology, persistence of seeding activity, resistance to standard decontamination, source and concentration of the material, route and scale of exposure, use of human- or animal-derived pathological tissue, and procedures

involving inoculation, sharps, aerosols, or other opportunities for occupational exposure. Routine work with non-seed-competent monomeric proteins or aggregates lacking evidence of biological propagation would not ordinarily require specialized biosafety review beyond the requirements otherwise applicable to the experimental system, and we recommend that the Delegated Review mechanism described in Section IV-3 be applied to such work.

• The scope of the draft Policy includes toxins listed as Select Agents, and research activities involving these materials would require IBC review and approval under Section IV-2, while research with biological toxin proteins not on the Select Agent list may be approved by Delegated Review under Section IV-3. We support this overall approach; however, we request refinement of the Policy with the following recommendations.

• Recommendation 1: Allow research activities using exempt amounts of Select Agent toxins to be approved by Delegated Review. Most institutions have already developed effective internal biosafety oversight mechanisms for handling these exempted materials. Integrating those internal oversight mechanisms into the Delegated Review process would allow IBCs to focus on the higher-risk Select Agent work.

• Recommendation 2: Either publish a list of biological toxins that fall within the scope of the Policy or use a threshold toxicity value as a risk-based factor for determining whether a biological toxin requires oversight by the Policy. We further recommend that biological toxins that have an LD_{50} greater than 1000 µg/kg be exempt from this Policy.

• The scope of the draft Policy includes cells, viruses, or organisms, other than plants, that have been genetically modified. It is assumed that animals are included as organisms, but it is not clear what is considered an animal under this Policy.

• Recommendation: Use a definition of animal that is consistent with the Guide for the Care and Use of Laboratory Animals, which has been adopted by the NIH Office of Laboratory Animal Welfare, and which defines animals as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

• The draft Policy indicates that the effective date will be 6 months from publication of final Policy, and that applicability includes ongoing work. It is unclear how ongoing work will be impacted by the new review and approval requirements. Work that was not subject to IBC oversight according to the NIH Guidelines may have been approved via voluntary institutional biosafety oversight mechanisms.

• Impact: Work that was approved by a Biosafety Officer (or other institutional biosafety oversight) and now requires a higher level of review by the IBC would need to cease until IBC approval is obtained. This would have a significant negative impact on a large number of projects that are suddenly subject to new oversight, thereby wasting grant money and setting back important research projects.

• Recommendation: Require activities that have not received approval by a Biosafety Officer or other institutional biosafety oversight mechanism to be reviewed and approved according to the final Policy within 6 months of the publication of the final Policy. For activities that have received approval by a Biosafety Officer or other institutional biosafety oversight mechanism, allow the existing approval to remain in place until such time as de novo registration is required (see point 2 regarding our recommendation to allow 5-year term limits for IBC registration approvals).

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

417. UMass Chan Medical School

I am responding: On behalf of an organization

Name: John Erwin

Name of Organization: UMass Chan Medical School

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: UMass Chan Medical School supports the objective of modernizing biosafety oversight to address genuine and evolving biological risks. However, we are concerned that the proposed definition of "genetic modification" contained in the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112), specifically the provision that classifies introduced nucleic acid molecules as genetic modifications if they "can be transcribed or translated" believe is too broad and could have unintended consequences that run counter to the states objective of the Draft Policy.

This criterion is overly broad, scientifically imprecise, and insufficiently connected to biological risk. The proposed change could substantially expand the scope of biosafety oversight to encompass routine molecular biology, cell biology, and biomedical research that do not produce a meaningful change in the properties or hazards.

Without clear limits, investigators and institutions could be required to interpret a wide range of ordinary experimental materials as "genetic modifications". This ambiguity could result in inconsistent Institutional Biosafety Committee (IBC) determinations, unnecessary administrative burdens, delays in otherwise low-risk research as well as significant confusion in the general public by significantly expanding the definition of "genetic modification."

Such an outcome would be difficult to reconcile with the draft policy's stated objective of calibrating oversight to risk and reducing unnecessary administrative burdens on low-risk research.

Biosafety oversight should be based on demonstrable or reasonably foreseeable hazards and urge NIH to revise this provision before finalizing the policy, replacing a capability-based trigger with a scientifically grounded, clearly defined, and risk-proportionate standard. Such a revision would preserve meaningful biosafety protections while reducing regulatory ambiguity, unnecessary administrative burdens, and avoidable impediments to biomedical research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

418. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Other

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 261014-ABSA-NIH-Biosafety-Policy-Comments.pdf_5217.pdf

ABSA International — The Association for Biosafety and Biosecurity

Organization:	ABSA International 1200 Allanson Road, Mundelein, IL 60060 Phone: (866) 425-1365 | Email: info@absa.org | Web: www.absa.org
Date:	October 19, 2026
To:	Office of Science Policy National Institutes of Health 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892
Submission Portal:	Submitted via NIH OSP Electronic Comment Portal
Subject / Notice:	Formal Public Comments and Recommendations on the Draft NIH Biosafety Policy for Research Involving Biohazards (Notice Number: NOT-OD-26-112)

ABSA International, the Association for Biosafety and Biosecurity, is a nonprofit professional association representing biosafety and biosecurity professionals in the United States and internationally. Our membership spans academic and research institutions, government laboratories, biotechnology companies, healthcare organizations, public health agencies, and consulting practices. Members bring scientific, technical, operational, and regulatory expertise across diverse biological research and laboratory settings.

ABSA's comments reflect the practical experience of professionals responsible for translating biosafety policy into daily practice. Our members conduct risk assessments, support Institutional Biosafety Committees (IBCs), develop training and containment practices, investigate incidents, and advise institutions on compliance. They understand how policy requirements affect laboratory safety, reporting culture, institutional resources, and the conduct of research.

NIH's commitment to gold standard science provides an opportunity to establish an equally high standard for biosafety oversight. Clear, science-based, and risk-informed requirements can make gold standard biosafety an integral part of rigorous research and reinforce public

confidence in NIH-supported science. ABSA supports NIH's efforts to strengthen biosafety oversight. We offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment while enabling responsible scientific research.

The volume and technical depth of the comments below, together with the significant concerns raised by the broader scientific community, demonstrate that the draft Policy cannot be implemented effectively in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

NIH Form Categories

1. Policy scope, definitions, and gaps of oversight
2. Tiered oversight and calibration to risk, including federal versus local oversight
3. Continued utility of Risk Groups versus Biosafety Levels
4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).
5. Draft Incident Reporting and Meeting Minutes Templates
6. Implementation resources and areas needing additional guidance

CATEGORY 1.0: POLICY SCOPE, DEFINITION OF BIOHAZARDS, AND APPLICABILITY

***Topic to Address**: Appropriateness of the scope of the new policy, including the definition of biohazards, for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.*

Comment 1.1: Policy Section II, Scope - Clarify the scope of the policy.

Title, scope, and intent. The Policy's title suggests a general biosafety framework, but its scope, "biomedical research, in laboratory settings, involving biohazards," ties it to human health under NIH's mission. The title, scope, and stated intent should be consistent.

Scope limitations and One Health. The Policy's scope is limited by an overarching criterion of known or potential risk to human health. It excludes plants from specified genetically modified categories and does not clearly cover hazards affecting only animals, plants, agriculture, or the environment. This narrower scope is difficult to reconcile with the One Health approach, and leaves unclear how NIH will coordinate with the federal programs responsible for those areas. Any resulting gap would fall to other agencies to address. This was a key concern raised in every listening session.

Internal inconsistencies. Despite this human-health scope, several provisions address animal and environmental considerations. Section III-B references agricultural animals and environmental protection. Sections V-A and V-B address the population-level and environmental impacts of GDMOs. The "prion" definition refers to disease "in humans or animals." These provisions do not fit within the scope as written.

Recommendation. NIH should resolve these inconsistencies in one of two ways:

1. **Broaden the scope** to a One Health approach, developed in collaboration with other funding agencies, that ensures adequate oversight of animal, plant, and environmental hazards while minimizing administrative burden; or
2. **Limit the scope explicitly** to hazards to human health, align the title accordingly, and revise the provisions identified above for consistency.

Common 1.2: Clarify the "known or potential risk to human health" threshold for Policy scope

NIH should clarify how the "known or potential risk to human health" threshold in Section II is intended to determine whether research falls within the scope of the Policy. Section II

defines covered research as biomedical laboratory research involving a known or potential risk to human health and one or more specified categories of biohazards. However, Section IV-3 establishes oversight categories for several types of relatively low-risk research, including genetically modified RG1 biological agents, BSL-1/ABSL-1 transgenic organisms, well-characterized cell lines, and certain plasmids and low-risk transgenes. NIH should clarify whether inclusion in one of the enumerated biohazard categories is itself sufficient to establish a "potential risk to human health," or whether institutions must first make a separate determination that the research presents such a risk. If a separate threshold determination is required, NIH should provide criteria and representative examples for making that determination. Clear guidance is needed so institutions can consistently distinguish research that is outside the scope of the Policy from research that falls within scope but qualifies for a lower tier of oversight.

Reference basis: Draft NIH Biosafety Policy for Research Involving Biohazards, Section II (Scope) and Section IV-3.

Comment 1.3: Policy Section II - Clarify how clinical settings fit within the definition of laboratory research [Section II (definition of Laboratory research) and Section V-E.]

Inconsistency. Section II defines laboratory research as research conducted in BSL/ABSL-1 through BSL/ABSL-4 containment facilities, including vivarium, core facilities, and clinical settings. Section V-E, however, acknowledges that clinical research involving the handling and administration of potentially biohazardous materials often occurs in clinical settings that do not conform to laboratory biosafety levels. It is unclear how such settings satisfy the Policy's "laboratory setting" criterion.

Interpretation. We do not read the draft Policy to require IBC oversight of routine clinical or diagnostic activities. For an activity to be covered, it requires biomedical research involving an in-scope biohazard within a laboratory setting.

Recommendation. NIH should:

1. Clarify how a clinical environment that does not conform to a laboratory BSL satisfies the "laboratory setting" scope criterion.

2. Define the boundaries among protocol-required clinical procedures, research specimen processing, research-associated diagnostic testing, standard-of-care testing, and routine patient care.
3. Specify the risk assessment and control framework expected for covered research conducted in non-laboratory clinical settings.

Comment 1.4 - Clarify applicability to downstream clinical sites and products developed with NIH funding

NIH should clarify whether clinical studies involving products developed with NIH funding remain subject to the draft Policy when the subsequent clinical study is not itself NIH-funded.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-C-1-a-(2)*, explicitly cover certain human studies involving materials containing recombinant or synthetic nucleic acids that were developed with NIH funds, when the institution that developed the material sponsors or participates in the subsequent clinical study. The NIH Guidelines also require IBC approval from the clinical trial site before covered human gene-transfer research may begin.

The proposed *NIH Biosafety Policy for Research Involving Biohazards* does not clearly state whether this existing connection to NIH-funded product development will continue. For example, a product could be developed with NIH funding and later evaluated in a clinical study that receives no NIH funding and is conducted at a clinical site that does not otherwise receive NIH funding. It is unclear from the proposed Policy whether that clinical study and clinical site would remain subject to NIH biosafety requirements solely because the product was originally developed with NIH support.

Recommendation. The final Policy should continue the existing approach and say so expressly:

1. **Coverage:** The Policy applies when the institution that developed the product sponsors or participates in the study (including through collaboration or contractual agreements, but not mere provision of materials or licensing).
2. **Responsibility:** That institution must ensure the clinical site obtains IBC approval before the study begins, documented in its site agreement and Biosafety Assurance.
3. **Limit:** NIH funding of the original development does not, by itself, extend the Policy to independent studies at unrelated sites.

Suggested text for Section II: "This Policy also applies to research involving testing in humans of products developed with NIH funds, if the institution that developed those products sponsors or participates in the research. The sponsoring or participating institution is responsible for ensuring that the clinical site obtains IBC review and approval before the research begins."

Rationale. This keeps a rule that already works, places responsibility on the party able to act, and avoids obligations for sites that cannot know a product's funding history.

Related request. Please confirm whether gene-transfer products that do not shed, replicate, or integrate remain subject to IBC review under Section IV-2, since the draft's clinical category is narrower than the Guidelines' human gene transfer definition (Section III-C-1).

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-A-1-a, I-C-1-a-(2), I-C-1-b-(2), and IV-B-1-f. Draft NIH Biosafety Policy, Sections II and IV-2.

Policy Section II, Scope - Clarify oversight related to genetically modified and/or transgenic animals.

Comment 1.5: The definition of "genetic modification" expands scope significantly

The draft definition includes stable genome alterations introduced by passaging, reassortment, chemical means, or radiological means. This breadth creates uncertainty about where genetic modification ends, and the following begin, naturally occurring adaptation, intentional selection, laboratory-induced change, chemical or radiological exposure.

Examples of work that may or may not be covered include serial passage of a virus in cell culture, chemical mutagenesis of animals or cell lines, irradiation, and selection for drug resistance. These changes could require institutions to identify research activities that have not historically been overseen by the IBC. IBCs would need to develop new review processes, expertise, or administrative mechanisms to support compliance.

Comment 1.6: Clarify treatment of low-risk transgenic rodent activities and existing exemptions

Issue. Section II limits the Policy to research involving "known or potential risk to human health." Section IV-3, however, places all research with transgenic organisms at BSL-1/ABSL-

1 in a category requiring prior approval by delegated review, without regard to risk. The draft does not address breeding, purchase, or transfer. The current NIH Guidelines (April 2024) exempt the purchase or transfer of BL1 transgenic rodents (Appendix C-VII) and the breeding of qualifying BL1 transgenic rodents (Appendix C-VIII, adopted at 76 FR 3150). The Guidelines also treat generation of BL1 transgenic rodents under Section III-E-3, which requires registration at initiation but not prior to approval. The draft does not say whether these exemptions continue, so institutions cannot tell whether it is intended as risk-based streamlining, an expansion of review, or both.

Recommendation. The final Policy should apply the Section II threshold to transgenic animal research and adopt the following three tiers:

Tier	Activities	Review
Exempt from the Policy	Breeding, maintenance, cryopreservation, rederivation, transfer, and use of established transgenic animal lines, where the animals can be housed at ABSL-1 and (a) no parental line or expected progeny contains more than one-half of the genome of an exogenous eukaryotic virus from a single viral family, and (b) no transgene is under the control of a functional gammaretroviral long terminal repeat (LTR).	No IBC submission required
Delegated review (Section IV-3)	Generation of new transgenic animal lines at ABSL-1 (e.g., pronuclear injection, CRISPR editing, in vivo delivery of viral vectors) and any change that alters the original risk assessment.	Individual IBC member or subgroup
Full IBC (Section IV-2) or NIH (Section IV-1) review	Activities involving significant biological hazards or uncertainty, including infectious-agent generation or mobilization, hazardous transgene expression, or consequential gene drive activity.	Full IBC; NIH where Section IV-1 applies

Rationale

- **Consistency with the draft's scope.** Most transgenic lines (knockouts, fluorescent reporters, conditional alleles, Cre drivers) present no known or potential risk to human health. Oversight should follow the risk the Policy exists to address.
- **NIH's 2011 finding (76 FR 3150).** NIH concluded that decades of experience showed that breeding BL1 transgenic rodents almost always yields BL1 progeny and poses no appreciable risk to human health or the environment, and that the cumulative

registration burden was not commensurate with that risk. The draft cites no evidence that this conclusion has changed.

- **Burden and focus.** Requiring approval, amendment review, three-year renewal, and public posting of minutes for routine colony work conflicts with the draft's stated aim of removing red tape for low-risk research and diverts IBC attention from higher-risk work.
- **Existing oversight.** IACUC-approved protocols already track animal colonies, and the draft seeks consistency with IACUCs.

Suggested regulatory text (new exemption, or a note to Section IV-3):

> *Breeding, maintenance, transfer, and use of established transgenic animal lines are not subject to this Policy if the animals can be housed at ABSL-1 and (1) neither parental line, nor any expected progeny, contains more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses, and (2) no transgene is under the control of a functional gammaretroviral long terminal repeat. Generation of new transgenic lines remains subject to Section IV-3.* IBC review classification shall reflect biological hazards and experimental activities, not solely institutional housing containment assignments. Institutions may require additional containment without triggering a higher federal review category.

Request. We ask NIH to adopt this structure in the final Policy or, if it declines, to explain what has changed since 2011 and whether breeding of previously approved lines requires new approval.

Comment 1.7: Clarify oversight of transgenic agricultural and food-producing animals (Policy Sections II and IV-3)

The draft Policy does not clearly distinguish transgenic laboratory animals from transgenic agricultural or food-producing animals. Applying the same oversight approach to both groups may overlook material differences in potential consequences. Genetic modifications in agricultural animals may have implications beyond the individual research animal, including animal health, breeding populations, food production, environmental release, and interactions with other agricultural or ecological systems.

The Policy should therefore specifically address transgenic agricultural and food-producing animals and clarify how the Section II threshold of "known or potential risk to human health" applies when relevant risks may arise indirectly through animal health, agriculture, food systems, or environmental pathways.

Summary of recommendation. We recommend that the final Policy (1) distinguish transgenic agricultural and food-producing animals from routine transgenic laboratory rodent activities, (2) require an institutional biosafety risk assessment for the creation and use of transgenic agricultural animals, including consideration of animal, agricultural, environmental, and food-system consequences where applicable, and (3) establish risk-proportionate review pathways based on the nature of the genetic modification and the credible consequences of release, reproduction, or entry into agricultural systems.

This requirement should apply to animals whose genomes meet the draft Policy definition of a transgenic animal. Administration of DNA, RNA, recombinant or synthetic nucleic acids, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal should not, by itself, cause the animal to be classified as transgenic. Such research should instead be evaluated based on the properties and risks of the administered material and the experimental activity.

Rationale.

- *Agricultural animals present risk pathways not ordinarily associated with laboratory rodent colonies.* Agricultural animals may enter breeding populations, interact with conventional livestock, enter or affect food-production systems, or be maintained in environments where containment differs substantially from traditional laboratory animal facilities. These pathways should be considered when determining the appropriate level of oversight.

- *Human health cannot be considered independently of animal, agricultural, and environmental health.* A modification that presents little direct occupational risk may nevertheless have potential consequences through animal disease, food production, environmental release, or effects on agricultural populations. A biosafety framework should recognize these interconnected pathways rather than limiting assessment to direct laboratory exposure.

- *Oversight should focus on the genetic modification and its credible consequences.* The mere presence of administered DNA or RNA should not make an animal transgenic. The relevant distinction is whether the animal itself has undergone a stable genomic modification and whether that modification creates a credible biosafety, agricultural, environmental, animal-health, or food-system consequence.

- *Existing animal-use oversight does not replace biosafety review.* IACUC review addresses animal care and use but does not necessarily evaluate the full range of biosafety, environmental, agricultural, food-chain, or population-level consequences associated with a transgenic agricultural animal. Where those risks exist, biosafety review provides a distinct function.

- *Oversight should be coordinated across applicable authorities.* Transgenic agricultural animal research may fall within the jurisdiction or expertise of multiple federal agencies. NIH should clarify how its institutional biosafety requirements interface with USDA, FDA, and other applicable federal authorities so that responsibilities are clear and duplicative review is minimized.

Proposed oversight structure.

1. **Institutional biosafety risk assessment:** Creation or use of a transgenic agricultural or food-producing animal should undergo an institutional biosafety risk assessment that considers, as applicable:

    a. the nature and stability of the genomic modification;

    b. whether the modification is heritable and the potential for transmission through breeding;

    c. effects on animal health, phenotype, host range, susceptibility, or disease;

    d. potential entry into breeding or food-production systems;

    e. potential environmental release or interaction with non-research animal populations;

    f. whether the modification involves sequences derived from RG2 or higher agents, toxins, gene drive systems, or other genetic elements with elevated risk; and

    g. applicable federal, state, or other regulatory oversight.

2. **Delegated review under Section IV-3:** Transgenic agricultural animal research may be eligible for delegated review when the institutional risk assessment demonstrates low biosafety risk, the animal can be maintained under appropriate ABSL-1 or equivalent agricultural containment conditions, and there are no credible elevated animal-health, environmental, agricultural, or food-system consequences.

3. **Full IBC review under Section IV-2:** Full IBC review should apply when the modification presents credible higher-consequence risks, including potential effects on animal health or agricultural populations, environmental establishment, food or breeding systems, or when containment above ABSL-1 or equivalent agricultural containment is warranted.

4. **NIH or other federal review, as applicable:** Research presenting risks within the jurisdiction of NIH or another federal agency should follow the applicable federal review pathway. NIH should identify when another agency's review may satisfy or substitute for specific NIH requirements and which institutional biosafety responsibilities remain.

Proposed regulatory text. NIH should add the following clarification to Section IV-3:

Transgenic agricultural and food-producing animals. Research involving transgenic agricultural or food-producing animals shall undergo an institutional biosafety risk assessment before initiation. The level of IBC review shall be commensurate with the nature of the genetic modification and the potential consequences to human or animal health, agriculture, food systems, or the environment. An animal shall not be considered transgenic solely because it is administered DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material that does not integrate into the animal's genome and is not capable of autonomous replication or stable maintenance within the animal.

Request. We request NIH to distinguish transgenic agricultural and food-producing animals from routine low-risk laboratory rodent activities and establish a risk-based review framework that accounts for the additional animal-health, agricultural, environmental, and food-system consequences that may arise from stable genetic modification of these animals.

Comment 1.8: Define the coverage of recombinant and synthetic nucleic acids

In Policy Sections II and IV, NIH should clarify the status of standalone recombinant or synthetic nucleic acid research under the draft Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B and III-F, explicitly define recombinant and synthetic nucleic acid molecules and establish exemptions for certain standalone nucleic acids, including specified molecules that are not contained within organisms, cells, or viruses.

The proposed NIH Biosafety Policy instead defines scope primarily through biological agents and genetically modified cells, viruses, and organisms and does not explicitly state how standalone recombinant or synthetic nucleic acids are treated, while Section IV-3 separately identifies certain plasmid research as eligible for delegated review. NIH should clarify

whether standalone nucleic acids are intentionally outside the scope of the new Policy and, if not, identify the circumstances under which they become covered and the applicable oversight category. Explicit clarification would help institutions distinguish intentional risk-based streamlining from an unintended gap in scope.

Reference basis: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-B, III-F-1, and III-F-2. Draft NIH Biosafety Policy, Sections II, IV-3, and V-C.

Section II, Definitions

Comment 1.9: Policy

- The draft policy uses the term "**biological agent**," which is closely associated with biological weapons, notably in 18 U.S.C. § 178 and the Biological Weapons Convention. Although the term also appears in the Select Agent regulations (42 CFR Part 73), the Policy's scope extends well beyond select agents. We recommend replacing "biological agent" with "infectious microorganism or biological material," consistent with *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This would align the Policy with established biosafety terminology, and the risk assessment framework institutions already use, without implying a weapons or security context.

- The draft policy uses the term "**adventitious agents**" in three places without defining it: Section IV-2, which requires IBC approval before initiation for research with "primary cells that may be contaminated by adventitious agents"; Section V-A, which says primary cells and tissues may harbor them; and the incident reporting provisions, which exempt post-exposure treatment given for the potential presence of adventitious agents from NIH reporting unless a laboratory-acquired infection results. Without a definition, it is unclear whether work with such materials is within scope under Section II, and read literally, "may be contaminated" could sweep in nearly all primary cell work, including cells from low-risk sources, which conflicts with Section IV-3's delegated review of well-characterized cell lines. It also leaves institutions unable to apply the reporting exception consistently.

  We recommend that NIH remove the requirement or (1) define the term, for example as an unintended biological agent present in cells, tissues, animals, or reagents that was not

deliberately introduced and is not part of the planned research; (2) replace "may be contaminated" in Section IV-2 with risk-based criteria tied to the source and screening status of the material (for example, unscreened primary human or non-human primate cells), so that lower-risk primary cells fall under Section IV-3 or outside the Policy; and (3) clarify how the term relates to the Section II scope and the incident reporting exception, referencing existing BMBL and OSHA bloodborne pathogen guidance rather than creating new standards.

- The phrase "**potential risk to human health**" is undefined and ambiguous. As written, it could encompass hazards unrelated to biological materials, such as chemical, radiological, physical, or ergonomic hazards, which are already regulated by other federal agencies, including OSHA, EPA, and NRC. We do not believe NIH intends to extend the Policy to these hazards. The draft also does not specify who determines whether the threshold is met or what standard applies. We recommend that NIH:

    a. Define "potential risk to human health" as the potential to cause human disease or adverse health effects arising from the infectious microorganisms or biological materials within the Policy's scope.

    b. State explicitly that the Policy does not address non-biological hazards.

    c. Specify who determines whether the threshold is met (e.g., the Institutional Biosafety Committee) and the standard to apply, such as a risk assessment consistent with BMBL.

- The draft policy does not define "**Transgenic animal**." We recommend that NIH provide a definition and clarify that administering DNA, RNA, recombinant or synthetic nucleic acid molecules, or other genetic material does not by itself make an animal transgenic, provided the material does not integrate into the animal's genome and is incapable of autonomous replication or stable maintenance. We suggest the following:

    Transgenic animal: An animal whose genome has been intentionally modified through the introduction, deletion, replacement, or alteration of genetic material, such that the modification is stably incorporated into the animal's genome or germline and maintained through cellular replication, regardless of whether it is heritable by offspring.

- The proposed definition of "**prion,**" as *misfolded forms of proteins that can self-propagate and cause neurodegenerative disease in humans or animals,* is inconsistent with the Policy's scope. It references neurodegenerative disease "in humans or animals," whereas

the Policy is limited to risks to human disease. This would expand coverage to prion diseases of animals while excluding animal diseases caused by other etiologic agents. We recommend that NIH revise the definition to align with the Policy's scope, or address animal disease consistently across all agent types.

- The proposed definition of "**Toxins**" should include only those of living biological origin (plants, bacteria, fungi, viruses, etc.). This term does not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (aka "sensitizers").

- Define **"peptide"** as a molecule consisting of two or more amino acids linked by peptide bonds, generally shorter than 50 amino acids and capable of having biological activity depending on its sequence, structure, concentration, and context.

- Retain reassortment and non-transgenic methods within the "**genetic modification"** definition. Clarify whether incidental genomic changes from routine passaging are included or whether the definition applies to deliberate genetic alterations. Address how this distinction applies to reverse genetics and viral rescue systems, including recovery of wild-type organisms, and provide examples distinguishing routine maintenance from intentional modification.

- Define "**gene drive modified organisms"** and the acronym of GDMO consistently with the existing definitions of gene drive and genetic modification. This will help institutions apply the associated membership, containment, and review requirements consistently.

- Define "**shedding**" for purposes of determining IBC oversight of clinical research and clarify whether the term refers to release of biologically active or potentially transmissible material rather than detection of nonviable material or nucleic acid alone. Section IV-2 requires full IBC review for clinical research involving products capable of "shedding, replicating, or integrating," and Section III-B identifies shedding as a biosafety consideration for research involving human participants. However, the Policy does not define shedding or establish the characteristics that make shedding relevant to biosafety risk. FDA's Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products defines shedding as release of the administered product from a patient and distinguishes shedding from biodistribution; the guidance also frames transmission concerns around release of intact virus or bacteria rather than degradation products such as nucleic acid fragments. NIH should define "shedding" for purposes of this Policy, consider harmonization with relevant FDA terminology where appropriate,

and clarify whether detection of noninfectious or non-biologically active material alone is sufficient to place a clinical study within the full-IBC-review category.

Reference basis: Draft NIH Biosafety Policy, Sections III-B and IV-2. U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015).

- Use of "**Universal Precautions**" in clinical research settings. The draft states "*However, precautions to protect personnel must include the use of universal precautions such as gloves, and eye and respiratory protection.*" We recommend revising the sentence to use current, risk-based infection-prevention terminology (*Standard Precautions*) and to clarify that the selection of PPE must reflect the hazards associated with the research materials and procedures being performed.

Section II: Gaps of Oversight

Comment 1.10: Biosafety Officer: Designation, Qualifications, Standing, and Institutional Capacity

Policy Sections III-A; III-B (IBC Membership; Biological Safety Officer); Biosafety Assurance

ABSA International believes the draft Policy misses an important opportunity to support the biorisk management field. It fails to describe the qualifications of a biosafety/biorisk professional; furthermore, it omits details outlining their role, standing, and the critical institutional support needed to ensure the Biological Safety Officer (BSO) can effectively execute their duties. In our March 2026 response, ABSA International requested that NIH clearly define the requirements, roles, and responsibilities of a BSO as it relates to this proposed policy implementation and IBC oversight; however, the current draft is still lacking these vital details. As currently written, the policy only lists four (4) duties and ties the NIH's requirement for a BSO exclusively to the presence of BSL-3/BSL-4 laboratory or gene drive research and allows institutions without a BSO to assign "another official" for which no minimum qualifications are outlined.

As this vital component was omitted from the original draft, ABSA International welcomes the opportunity to collaboratively define the minimum qualifications that would allow an institution to meet any modernized biosafety policy.

Designation. ABSA International does not support limiting the BSO requirement to institutions that only conduct research at BSL-3, BSL-4, or with gene drive modified organisms. While the draft greatly expands the Policy's scope to include wild-type agents, genetically modified cells and organisms, toxins, prions, and clinical research, it fails to consider that a vast majority of this type of work occurs at BSL-2; therefore, leaving a large oversight gap. Additionally, this policy presents a very narrow scope of oversight which eliminates the requirement to assess risks associated with animal, plant, and arthropod associated pathogens. ABSA International recommends that NIH base the BSO requirement off each institution's research portfolio and risk profile, not exclusively on the three (3) aforementioned qualifiers.

The draft policy also adds additional regulatory burden on the BSO, their designee, and any associated staff by requiring substantial work including:

- Periodic inspections
- Incident response and investigation
- 24-hour notification
- 30-day reporting to NIH
- Delegated review
- Technical advice
- Petitions to NIH
- Enhanced reporting of IBC minutes

Minimum qualifications. Where a BSO is required, the NIH should define minimum qualifications and outline the need for direct access to leadership/authority to support the identification and escalation of unresolved risks. In that light, ABSA International recommends a broad statement of qualifications rather than a mandatory degree or credential. This approach is consistent with ABSA's earlier position that such mandates would create unnecessary barriers to entry and potentially disqualify highly qualified personnel. Please consider the below proposed language:

The BSO shall be qualified through a combination of education, training, and experience commensurate with the biohazards, containment levels, and complexity of the institution's research. Qualifications should generally include:

- *Education in the biological or physical sciences, with knowledge of microbiology and molecular biology;*

- *demonstrated competence in biological risk assessment and risk mitigation, including containment practices, safety equipment, and facility design and operation;*
- *working knowledge of the Policy, the BMBL, and other applicable federal, state, and local requirements (e.g., the Federal Select Agent Program, import permits, and transport of biological materials) as applicable to their institution; and*
- *the ability to train, advise, investigate incidents, and communicate effectively with researchers, IBC members, regulatory agencies (as applicable), and institutional leadership.*

Institutions supporting BSL-3/ABSL-3, BSL-4/ABSL-4, gene drive research, or research subject to dangerous gain-of-function (DGOF) or international research of concern (IROC) oversight should ensure the BSO has demonstrated experience with those activities. Professional credentials, such as the Registered Biosafety Professional (RBP) and Certified Biological Safety Professional (CBSP), are recognized evidence of competence and are preferred, but are not required. Furthermore, institutions must provide ongoing support to the BSO's continuing professional development ultimately supporting institutional alignment with current guidance and regulations.

Institutional standing, access, and authority. The BSO's role should be that of a critical institutional official and should be comparable to that of an Attending Veterinarian regarding the authority to halt operations if prescribed procedures and practices are not adhered to. ABSA International recommends that each institution describe the following in its institutional plans/policies:

1. The BSO's reporting line has direct access to the Institutional Official and senior leadership;
2. access to all research spaces and records subject to the Policy;
3. authority to identify and escalate unresolved risks to the IBC and institutional leadership;
4. independence from the research units of which the BSO oversees, with protection from retaliation for good-faith safety determinations; and
5. staffing, resources, and funding for training, professional development, and credential maintenance that are in alignment with the research portfolio and risk profile.

Roles and responsibilities. The Policy should describe the BSO's role as a professional who administers or leads the institutional biosafety program and not merely focus on their role

as an inspector. In addition to the duties outlined in the Policy, the BSO's responsibilities should also include:

- Supporting PIs and the IBC with risk assessments and protocol pre-reviews;
- Serving as a voting IBC member and, where permitted, as a designated or delegated reviewer;
- Developing and delivering biosafety and biosecurity training;
- Leading or coordinating incident response activities, investigations, root cause analysis, verification of corrective actions, and NIH reporting;
- Assist with developing emergency response plans;
- Coordinating with occupational health on medical surveillance and post-exposure response;
- Advising on biosecurity, inventory, and material transfer;
- Preparing or assisting with NIH containment petitions; and Supporting the institution's DGOF and IROC determinations and coordinating with its institutional review mechanism and designated institutional contact.

Operational duties may be assigned to qualified staff at the discretion of the BSO.

Officials assigned BSO responsibilities. For institutions not required to appoint a BSO, the draft permits another institutional employee to assume the BSO responsibilities. It is strongly recommended that guidance be established to define the minimum qualifications that an individual must possess. Conversely, where the NIH requires a BSO, institutional plans/policies should recognize that position as a distinct institutional authority, not simply another administrative assignment.

Staffing and expertise. The proposed Policy will affect institutions disproportionately, as entities that have not previously staffed a BSO position/biosafety office will need support and guidance on how to do so effectively. Institutions conducting high containment, high volume, or technically diverse research may need additional biosafety professionals, IBC administrative support, and IT/security capacity to appropriately manage the increased workload. Institutional plans/policies should therefore scale expectations to each institution's research portfolio.

NIH should consider the financial burden placed on institutions to meet the Policy requirements due to the potential anticipated need for additional specialized staff.

Due to anticipated increased workload and potential need for additional funding and staffing, ABSA International kindly requests that the NIH provide FTE estimates so that the financial burden associated with compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101) can be communicated to the greater biosafety community and their leadership.

Defining these expectations would set support and funding standards comparable to those for IRBs and IACUCs. It would also give institutional leadership a clear basis for planning and funding compliance with both this Policy and the USG Policy for Stopping High-Risk Life Sciences Research (NOT-OD-26-101). Under both policies, the BSO is often the institution's primary resource of risk assessment expertise. We recommend that the NIH implementation resources include a model BSO role description and associated competency guidance, developed in coordination with the biosafety professional community. This guidance could take the form of a matrix that scales expectations to institutional size and complexity.

Ultimately, the effectiveness of a modernized NIH biosafety policy depends not only on clearly defined requirements, but also on ensuring that institutions have qualified professionals, authority, and resources necessary to implement them. The BSO is central to translating policy into effective institutional practices, identifying and mitigating risks, and supporting a culture of safety that protects researchers, the public, the environment and the research enterprise. Expectations for this role must therefore be matched by appropriate institutional support and a realistic understanding of the staffing, expertise, and funding required for compliance. ABSA International encourages NIH to work collaboratively with the biosafety professional community to develop clear, scalable implementation guidance that reflects the diversity and complexity of institutional research programs. Establishing these expectations will help ensure that the revised Policy achieves its intended goals while supporting consistent, effective, and sustainable biosafety oversight across the research community.

Comment 1.11: Clarify the rationale and transition plan for removal of genetically modified plants and certain plant pathogens.

NIH should clarify the rationale and transition plan for removing plants, including genetically modified plants, from the scope of the new Policy. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) currently establish IBC

oversight and containment requirements for specified research involving genetically modified plants, including provisions addressing plant containment and potential environmental impacts. In contrast, Section II of the proposed NIH Biosafety Policy excludes plants from the covered categories of genetically modified cells and organisms, and NIH's August 2026 Table of Changes expressly states that genetically modified plants and plant pathogens that do not cause human disease will not be covered. NIH should clarify the policy with the Table of Changes and clarify the rationale for this change, how institutions should transition research currently overseen under the April 2024 NIH Guidelines, and what oversight NIH expects for contained plant research presenting biosafety or environmental risks when no other Federal requirement applies. This clarification would help institutions distinguish an intentional change in NIH jurisdiction from activities for which continued institutional biosafety oversight may remain appropriate.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections III-D-5 and III-E-2 and associated plant-containment provisions. NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026).

CATEGORY 2: TIERED OVERSIGHT AND CALIBRATION TO RISK, INCLUDING FEDERAL VS LOCAL OVERSIGHT

Comment 2.0 - Clarify when oversight by another Federal agency substitutes for NIH or IBC oversight

Section II of the proposed *NIH Biosafety Policy for Research Involving Biohazards* states that research subject to the Policy that is also under the regulation or purview of another Federal agency may proceed under that agency's oversight once applicable approvals or clearances have been obtained.

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1*, contain a similar provision, but it is more specific: approval by another Federal agency with jurisdiction can substitute for NIH review or approval. It does not state that required institutional IBC oversight is also eliminated.

The broader wording in the proposed Policy could therefore be interpreted to mean that another Federal agency's oversight may replace not only NIH review, but potentially institutional requirements such as IBC review and approval.

NIH should clarify whether this provision is intended only to avoid duplicative Federal review or whether oversight by another Federal agency can also satisfy institutional IBC requirements. NIH should also identify which Policy requirements, such as IBC review, institutional biosafety oversight, incident reporting, and what other requirements remain applicable when another Federal agency has jurisdiction over the research.

Reference basis: Draft NIH Biosafety Policy, Section II. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section I-A-1.

Comment 2.1 - Clarify the institutional boundaries of the expanded applicability to non-NIH-funded research

NIH should clarify the institutional boundaries and implementation requirements associated with extending the Policy to non-NIH-funded research at institutions receiving NIH funding. Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2, the institutional trigger is NIH support for recombinant or synthetic nucleic acid research; once triggered, covered recombinant or synthetic nucleic acid research conducted at or sponsored by that institution is subject to the NIH Guidelines regardless of funding source. The proposed NIH Biosafety Policy materially broadens this by applying the Policy to covered non-NIH-funded biomedical research conducted at an institution that receives any NIH funding, irrespective of whether

that NIH funding supports research involving biohazards. NIH should clarify how "institution" and "sponsored by the institution" should be interpreted, particularly for organizations with multiple campuses, separately incorporated hospitals or research entities, affiliates, subsidiaries, shared IBC arrangements, contract research organizations, and research conducted at external sites. NIH should also clarify responsibility where more than one institution conducts or sponsors covered research. Clear organizational criteria will be important to ensure that institutions can identify all research subject to the Policy and avoid inconsistent interpretations across complex research organizations.

Reference basis: Draft NIH Biosafety Policy, Section II (Scope; Compliance and Enforcement). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Sections I-C-1-a-(1) and I-D-2.

CATEGORY 3 ADDRESSING: CONTINUED UTILITY OF RISK GROUPS (RGs) AS A BASELINE FOR RISK ASSESSMENT, PARTICULARLY WHEN AGENTS ARE BEING GENETICALLY MODIFIED, VERSUS USE OF BIOSAFETY LEVEL (BSL) OUTLINED IN THE BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES (BMBL).

Comment 3.0: Risk Groups should not serve as a classification that drives laboratory oversight

NIH asked about the continued utility of RGs as a baseline for risk assessment, particularly for genetically modified agents. We recommend that NIH remove RG "classifications" as a basis for oversight or redefine them as an informational reference only.

Why RGs are poorly suited to laboratory use:

- **They describe risk to healthy adults in the community.** Section V-A says RGs reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a coworker is healthy, and some individuals are more susceptible because of medications, immune status, or pregnancy.
- **They reflect community exposure, not laboratory conditions.** Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the community or environment.
- **They have no baseline for novel constructs.** Recombinant and synthetic nucleic acid work does not exist in the community until it has been studied in the laboratory, which is the purpose of the laboratory.
- **They cover only human etiologic agents.** The Policy's definition of biohazards is broader than agents that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
- **They are misinterpreted.** Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory personnel and for the environment outside the laboratory.

Recommendation: Retain the RG list, if at all, as one input to the first step of risk assessment (characterizing the hazard). Oversight categories in Section IV and containment decisions should rest on experiment-specific risk assessment and the BSL/ABSL framework. Section IV currently keys several categories to RGs (IV-1 through IV-3), and these should be revised accordingly.

Comment 3.1: The draft policy conflates RG classification with biocontainment level

The "IBC Functions" section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents "for which the RG classification or containment level is not available in the BMBL," and says the IBC may not approve such research "until authorized by NIH and any other applicable Federal, State, or local entities."

1. **The terms are not interchangeable.** Section V-E of the draft states that RGs and BSLs are related but not equivalent. The IBC Functions text nonetheless treats "RG classification" and "containment level" as alternative things that might appear in the BMBL. We ask NIH to use the terms consistently throughout.
2. **The BMBL does not assign RGs.** It provides agent summary statements with BSL recommendations. A condition referring to an RG classification "in the BMBL" cannot be met.
3. **The role of "and any other applicable Federal, State, or local entities" is unclear.** NIH should specify which entities this refers to, whether their approvals are sequential or concurrent, how they are coordinated, and what happens if determinations conflict.
4. **The scope of the petition requirement is unclear.** As written, the requirement may continue to apply to genetically modified non-pathogens and RG1 agents that are not specifically listed in the BMBL. NIH should state whether that is intended.
5. **Determinations should be published and reusable.** Section III-D commits NIH to publish approved determinations for lowering containment of RG3 and RG4 agents. It makes no equivalent commitment for emerging, novel, or zoonotic agents. We ask NIH to publish all containment determinations (agent, modification, determined containment, and rationale) in a searchable public resource that other institutions and investigators may rely on. This would avoid repeated petitions for the same agent and modification and reduce administrative burden. NIH should also set a target timeline for responding to petitions, since the draft says only "timely."

CATEGORY 4 ADDRESSING: MECHANISMS TO ENCOURAGE AND ACCOMODATE VOLUNTARY COMPLIANCE FOR RESEARCH NOT SUBJECT TO THE POLICY (e.g., AT NON-NIH FUNDED INSTITUTIONS).

No comment at this time.

CATEGORY 5 ADDRESSING: DRAFT INCIDENT REPORTING AND MEETING MINUTES TEMPLATES

Comment 5.1: Consider risk-proportionate public disclosure of biosafety incident reports and PI identification

NIH should reconsider whether identifiable public disclosure requirements are appropriate for all biosafety incidents subject to the Policy and clarify what information is necessary to achieve meaningful public transparency. Section III-B requires institutions to post all incident reports on a public-facing institutional website, including reports of lower-risk incidents that are managed institutionally and are not required to be reported to NIH. The Draft NIH Incident Reporting Template also requires identification of the Principal Investigator (PI) and does not permit redaction of the PI's name, as NIH excludes the PI from the exemption allowing individuals involved in an incident to remain unidentified. The stated rationale is that information already widely available from public sources, including PI names, biological agents, and grant numbers, may not be redacted. While ABSA supports appropriate transparency regarding significant biosafety incidents and institutional responses, we strongly urge NIH to carefully calibrate disclosure requirements to the significance and potential public health consequences of each incident. For lower-risk incidents that do not meet NIH reporting thresholds, de-identified reports, standardized summaries, or aggregated reporting may provide meaningful transparency and opportunities for community learning. NIH should also clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports and consider whether such identification is necessary when it does not materially contribute to understanding or preventing these incidents.

Reference basis: Draft NIH Biosafety Policy, Sections III-A and III-B. Draft NIH Incident Reporting Template (August 2026), "Redaction and Posting of Incident Reports" and Part 1.

Comment 5.2: Limit public content to information that supports transparency

NIH should not require routine public disclosure of:

1. Investigator's names
2. Grant numbers or internal project numbers
3. Sensitive animal research information
4. Select agent and toxin information
5. Proprietary materials and research outcomes

6. Identifying facility information
7. Other details that could compromise safety, security, or personnel protection

Personnel safety. In some areas of research, particularly animal research and other activities that have historically attracted harassment, threats, or targeting of researchers, public disclosure of investigator identities, funding information, or other identifying details may create risks to researchers and animal care personnel without a corresponding transparency benefit. These concerns also apply to information requested in the Biosafety Assurance statement, including continuously updated IBC rosters and contact information for IBC chairs, Biological Safety Officers, IBC contacts, and other individuals whose information is expected to be linked to the statement.

Research security. Publicly posted IBC meeting minutes could enable the aggregation of valuable intellectual property and research information over time and across institutions throughout the United States. Taken together, these records could reveal the biological agents institutions work with, the direction of unpublished research proposed by individual laboratories, the locations of high-containment research, and the number of facilities experiencing failures involving equipment, personnel training, standard operating procedures, or other safeguards. This information would be available to anyone, including foreign adversaries and other malicious actors. Such unprecedented access stands in stark contrast to federal research security policies and the Federal Select Agent Program's biosecurity measures and restrictions on security-sensitive information. We ask NIH to coordinate with federal research security and select agent authorities, including the Office of Science and Technology Policy, when establishing public disclosure requirements.

Alternative. NIH can meet its transparency goal by publishing aggregated, deidentified incident data through an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center. Full records should remain available to NIH and other authorized reviewers to support investigations of laboratory-acquired infections (LAIs) and other public health efforts.

Comment 5.3: Require content elements, not a rigid template

Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based

approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

Comment 5.4: Distinguish federal and state requirements

NIH should replace the term "appropriate and allowable" redactions with "specific and allowed" redactions that follow a set of standardized examples that allow the institutions to withhold information that poses a safety or security risk. State public-records laws vary and may affect what information institutions can redact. NIH guidance should distinguish between required federal posting and redaction standards from any additional disclosure and disclosure obligations imposed by applicable state laws.

Comment 5.5: Align reporting requirements with proportionate risk mitigation measures

The draft reporting requirements rely on ambiguous phrases such as "any incident," "loss of containment," "significant problems," and "minor spills... generally do not need to be reported," and fail to account for established engineering controls across biosafety levels. As currently written, the requirement to report "potential releases involving facility and/or equipment failures even when redundant systems were functioning properly" would treat a fully mitigated spill inside a biosafety cabinet as a reportable incident, without recognizing how containment engineering actively protects personnel and the environment (see table below). When redundant systems function properly and maintain containment, a facility or equipment component failure does not, by itself, result in a biological material release. In such a scenario, failure alone does not establish a potential release. This reporting requirement is therefore internally contradictory because it characterizes a failure as a potential release even when functioning redundant systems maintain containment and prevent a release. NIH should remove this phrasing from the Policy.

Comparative Containment Risk Profile: BSL-3 vs. BSL-4

Biosafety Level	Engineering Barrier Architecture	Incident Risk & Containment Impact
BSL-3 / ABSL-3	Primary containment (BSC/sealed cup) combined with directional negative airflow	A spill outside a BSC is considered a breach of primary containment, requiring room evacuation and air

	and 100% exhaust, and at times through HEPA filtration.	clearance. Directional airflow prevents room escape.
BSL-4 / ABSL-4 (Suit Lab)	Maximum containment: positive-pressure suits, air pressure resistant (APR) doors, airlocks with chemical showers, pass-through autoclaves, effluent treatment systems.	A spill outside a BSC is considered a breach of primary containment, however, personnel are fully encapsulated inside positive-pressure suits, eliminating the potential risk of exposure. Secondary/tertiary barriers actively prevent environmental release. Due to the type of personnel protective equipment used in the laboratory, room evacuation is not required. Both supply and exhaust air are HEPA filtered and additionally, APR doors prevent room escapes.

Proposed Recommendation: Four Calibration Rules for Section III-B

1. **Anchor 'Release' to Containment Boundaries:** Release means a failure in biosafety practice and/or equipment such that there is an escape of biological material beyond the defined biocontainment boundary.
2. **Calibrate by Biosafety Level:** Acknowledge that higher containment levels (BSL-4) possess redundant secondary envelopes that prevent environmental dissemination even during procedural disruptions.
3. **Define 'Exposures' and 'Medical Treatment':** Clarify that PPE/equipment failures in BSL-3/4 without active agent exposure are not reportable incidents. Align 'medical treatment' explicitly with OSHA standards (care beyond basic first aid).
4. **Eliminate Subjective Phrasing:** Remove vague terms like 'generally' in minor spill rules, and define 'significant violations' as non-compliance directly compromising containment or involving unapproved high-consequence research.

Appendix: Proposed Regulatory Text Amendments

To operationalize these recommendations, we propose the following specific amendments in the final policy:

Section II. General Definitions — Insert New Definition:

- **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.

- **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.

Category 6: Feedback on the implementation resources and areas in which additional guidance would be beneficial.

Comment 6.0: Provide risk assessment guidance for self-aggregating proteins

Policy Sections II and V-A

The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.

Comment 6.1: Clarify oversight of computational and AI assisted work

Policy Sections II and V-C

Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.

Comment 6.2: ABSA recommends the Retention in the Policy

Make BSL-3 enhanced and influenza occupational-health requirements authoritative and available before implementation

NIH should ensure that the requirements associated with “BSL-3 enhanced” containment and the required occupational health plan for specified influenza research are explicitly defined, authoritative, and available when the final Policy takes effect. Section V-E of the proposed Policy requires specified experiments involving 1918 H1N1, human H2N2, and certain HPAI H5N1 viruses to be conducted at BSL-3 enhanced containment and requires an occupational health plan. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7 and Appendix G-II-C-5, currently contain detailed containment, practice, training, animal-research, and occupational-health requirements. NIH has stated in NOT-OD-26-112 that implementation of resources will include information drawn from these existing provisions. ABSA supports preserving these risk-based protections and recommend that NIH clearly identify which requirements are mandatory, whether any requirements differ from the April 2024 NIH Guidelines, and the authoritative document in which the requirements will reside. Required implementation materials should be issued concurrently with the final Policy and sufficiently

in advance of the effective date to allow institutions to assess and demonstrate compliance consistently.

Reference basis: Draft NIH Biosafety Policy, Section V-E; NOT-OD-26-112 implementation-resource statement. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024), Section III-D-7, and Appendix G-II-C-5.

Primary Source Documents

- NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026) — https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
- NIH Office of Science Policy, NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (April 2024) — https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
- NIH Office of Science Policy, Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Policy_Table-of-Changes.pdf
- NIH Office of Science Policy, Draft NIH Incident Reporting Template (August 2026) — https://osp.od.nih.gov/wp-content/uploads/2026/08/Draft_Incident_Reporting_Template.pdf
- U.S. Food and Drug Administration, Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products: Guidance for Industry (August 2015) — https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-and-analysis-shedding-studies-virus-or-bacteria-based-gene-therapy-and-oncolytic-products

419. Environmental Health & Engineering, Inc. (EH&E)

I am responding: On behalf of an organization

Name: Nanette Moss, C.I.H., M.S.

Name of Organization: Environmental Health & Engineering, Inc. (EH&E)

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Genetics research (Basic research for development of medical therapies and clinical trials)

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Final-Comments-to-NIH-Policy-for-Biosafety-EHE.pdf

Description: The attached letter provides comments for your review and consideration regarding the proposed changes to biosafety oversight.

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Health & Engineering

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781-247-4300

COMMENTS FOR THE DRAFT NIH POLICY FOR RESEARCH INVOLVING BIOHAZARDS

Environmental Health & Engineering (EH&E) welcomes the opportunity to provide comments regarding the proposed National Institute of Health (NIH) Draft Policy for Research Involving Biohazards. EH&E is a consulting organization that works with numerous public institutions and private corporations as well as local regulatory agencies regarding life science research, biosafety, regulatory compliance and health risk analysis. As such, we have a unique and broad view of issues addressed in the draft "Policy" and appreciate that the NIH aims to update and improve biosafety oversight. Under the existing "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" we have had the opportunity to develop and manage many successful programs for our clients. We respectfully submit these comments for your review and consideration regarding the proposed changes to biosafety oversight.

Area of comment: Section IIIB *"Approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required."*

Comment: Many Institutional Biosafety Committees (IBCs) have established policies of de novo rewrite frequencies, which are commonly five-year terms, as well as established mechanisms to amend IBC registrations. Establishing a prescriptive three-year term for an IBC registration will significantly increase the workload for many IBCs as well as Principal Investigators without materially improving research safety.

Suggestion: Allow institutions to define de novo rewrite frequencies based on an internal assessment. Institutions may wish to align the timeframe with other compliance committees or by other operational factors. Additionally, allow the existing IBC research protocol approvals to remain valid until their scheduled renewal or expiration date.

Area of comment: Section II "*This Policy is applicable to all competing award applications, competitive revisions, proposals for contracts, and other funding agreements (e.g., Other Transactions, Cooperative Agreements) on or after [effective date will be 6 months from publication of the final Policy], and all existing awards and agreements as of that date. This Policy is applicable to all intramural research projects conducted on or after [effective date will be 6 months from publication of final Policy], including on-going or new studies. This Policy is also applicable to non-NIH funded research that is conducted on or after [effective date will be 6 months from publication of final Policy] at an institution that receives any NIH funding."*

Comment: The scope of the NIH policy would broaden oversight in certain areas that may have been approved previously for ongoing work by other institutional mechanisms (for instance toxins, certain cell lines, and wild-type organisms).

Suggestion: To limit disruption to ongoing research projects, institutions should evaluate timelines for IBC re-review of ongoing approved research projects. The six-month timeline for compliance should apply to new research projects and should begin after publishing all the final templates, definitions, and guidance documents in addition to the final "Policy".

Area of comment: Section IIIB "*Posting all incident reports on a public-facing webpage on the website of the institution, using the required incident reporting template.*"

Comment: Public transparency can make a valuable contribution to research safety when the community could be impacted by the proposed research activities. However, we believe public reporting of low-risk incidents with minimal impact on employee safety and no community risks can foster a level of concern that may be counterproductive, resulting in "information fatigue" or "over-warning", which dilutes attention and focus on the incidents that require more scrutiny. Additionally, incident reports rely heavily on worker cooperation and we are concerned that the proposed incident reporting requirements would discourage some employees from reporting.

Suggestion: Do not require institutions to publicly report: *Any incident involving research subject to the policy with an animal that is housed at BSL-1/ABSL-1 or BSL-2/ABSL-2 (e.g., bite, scratch, escape or improper disposition) or Any incident at BSL-1/ABSL-1 or BSL-2/ABSL-2 that does not involve agent-specific medical treatment when first aid is administered.* IBCs should review these incidents and ensure responses are appropriate and adequate and these will be captured in meeting minutes. Alternatively, U.S. Occupational Safety and Health Administration (OSHA) 300 Injury and Illness Logs, which are required to be posted at a facility, can be used as a reporting mechanism.

Are of comment: Section II *"For the purpose of the scope of this Policy, research involving biohazards is defined as research involving known or potential risk to human health and any of the following:*

1. *Wild-type biological agents (i.e., bacteria, viruses, fungi, or parasites) that cause disease in humans;*
2. *Cells, viruses, or organisms, other than plants, that have been genetically modified;*
3. *Toxins, prions, and other self-aggregating proteins; or*
4. *Cells or organisms, other than plants, containing 1, 2, or 3 above."*

Comment: Exemptions from Appendix F of the NIH Guidelines appear to have been removed. This will significantly increase the burden on the IBC and provide minimal benefit to research safety.

Suggestion: Define clear exemptions for hosts and vectors that present minimal risk to employees and no risk to the community. Retain the existing Section III-F-1 through III-F-8 exemptions and expand this category to include low risk plasmid cloning and protein expression in model organisms such as *Escherichia coli* (*E. coli*), BL21, and Caenorhabditis elegans.

Area of Comment: Section III-A Responsibilities of the Institution "*No research subject to this Policy may be conducted until the institution conducting the research has provided a written Biosafety Assurance through the Authorized Organizational Representative (AOR) that has been approved by NIH, setting forth compliance with this Policy. Assurances are approved by NIH for a period of up to four years. Assurance submissions will include:*

- Lines of authority and responsibility for administering the program and ensuring compliance with this Policy; to include contact information for relevant staff such as the IBC Contact, IBC Chair, and Biological Safety Officer (BSO) if applicable.
- To the maximum extent possible, weblinks to publicly-posted institutional biosafety procedures(including but not limited to documentation detailing the IBC roles, responsibilities, authorities, and processes for how biosafety risks are managed), a continuously updated IBC roster, IBC meeting minutes, incident reports, synopses of relevant staff trainings provided, and contact information for the IBC Contact, IBC Chair, and BSO (if applicable); information regarding whether the

institution conducts research in a Biosafety Level 3 (BSL-3)/Animal Biosafety Level 3 (ABSL-3) or BSL-4/ABSL-4 laboratory, research with gene drive modified organisms (GDMOs), has a BSO, receives NIH funding, and/or has an externally administered IBC.

Comment: We are concerned that the review and approval process will compromise research, given that work cannot proceed without NIH approval of the Biosafety Assurance Plan (BAP). All active, appropriately authorized research should be allowed to proceed, and there should be presumptive approval of a BAP after a reasonable review period (e.g., 30 or 60 calendar days after submissions) so that new research may begin only after appropriate IBC review and approval has been granted, where required. The requirement to post individual's names and contact information poses a potential security threat to those individuals. A single internet search of a person's name can reveal their home address and names of their family members including minor children. Given the range of unpredictable reactions to health science research , IBC personnel contact information should not be posted directly to the public. Furthermore, it is often difficult to recruit IBC members including community members given that the service on IBCs is voluntary. This additional risk will have the impact of deterring IBC membership and service.

Suggestion: Maintain the current system of submitting IBC rosters to NIH. Remove requirements to use individual's names on public facing websites.

Area of Comment (General): Increased documentation and administrative burden.

Comment: Increased documentation and administrative work will be needed for the proposed expanded scope of research requiring IBC review and approval, e.g., primary cells that may be contaminated by adventitious agents and research previously listed as exempt under Section III-F as well as the increased frequency of IBC de novo rewrite and submission (three years). The impact of this will be a shift of effort and personnel away from highly productive activities such as touring laboratories, meeting with researchers for small group training, and problem solving etc. to the office setting for generation and maintenance of documentation. It is important to recall that in 2025 the U.S. government moved to impose a cap on indirect costs (Facilities and Administrative costs) at 15% for all new and existing NIH grants. These proposed new administrative and documentation requirements per the proposed "Policy" would only add to such overhead costs with minimal or no enhancement to safety.

Suggestion: Minimize requirements for redundant or excessive IBC related documentation, reviews, and approvals such that institutional resources may be prioritized to activities shown to result in a greater research safety benefit.

Area of Comment: Review of comments and finalization of Biosafety Policy for Research Involving Biohazards.

Comment: The nature and scope of changes proposed in the new Biosafety Policy for Research Involving Biohazards are substantial. While many changes are welcomed by the new policy, some present substantial challenges to institutions.

Suggestion: Incorporate feedback from comments and publish a second draft policy for review. We agree with the efforts to modernize biosafety policy and believe this presents an excellent opportunity to better standardize the biosafety field. Careful and deliberate review will maximize the benefits of these efforts.

420. Ericka Pearce

I am responding: On behalf of myself

Name: Ericka Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): I submit these comments in my personal capacity as a Certified Biological Safety Professional (CBSP) with more than 23 years of experience supporting comprehensive biological safety and biosecurity programs in academic and federal research environments. Having worked closely with researchers, IBCs, IACUCs, institutional leadership, and federal agencies, I have seen firsthand both the challenges of conducting research and the realities of implementing effective biosafety policy. My comments reflect a belief that effective biosafety management programs should be evidence-based, practical to implement, and supportive of scientific discovery. In my experience, the best policies are those that make it easier to do the right thing, strengthen a culture of safety, and help researchers pursue innovative science safely and responsibly.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Comment 1: Modernization Should Not Become an Unfunded Mandate

I strongly support NIH's efforts to modernize biosafety oversight and expand the framework beyond recombinant and synthetic nucleic acid research to better reflect today's research landscape. The proposed policy appropriately recognizes that contemporary biosafety oversight extends beyond the scope envisioned when the NIH Guidelines were originally developed.

However, the draft substantially expands institutional responsibilities by introducing new requirements related to Biosafety Assurances, public transparency, incident reporting, training, documentation, protocol review, record retention, public posting, and oversight activities. While these new responsibilities may individually be reasonable, the draft does not identify corresponding resources or implementation support necessary to carry them out.

Real-World Implementation Impact
In a real research environment, these requirements will not be implemented by institutions in the abstract. They will be implemented by biosafety professionals, IBC administrators, investigators, laboratory personnel, occupational health staff, and institutional officials who already have extensive existing responsibilities.
Implementation is likely to require:

• Additional biosafety staffing;
• Administrative support personnel;
• New information management systems;
• Public-facing websites and document repositories;
• Incident-reporting infrastructure;
• Redaction and records-management processes;
• Expanded protocol tracking systems;
• New investigator and staff training programs; and
• Additional committee support activities.

At many institutions, particularly smaller universities, hospitals, teaching-focused institutions, and emerging research organizations, biosafety programs operate with limited staffing resources.

As a biosafety professional, I have observed that when new requirements are introduced without additional support, institutions often do not eliminate existing work. Instead, existing personnel absorb the additional responsibilities.

In practical terms, the same biosafety professional currently conducting laboratory inspections may also become responsible for reviewing public records, preparing redacted reports, maintaining websites, managing assurance documentation, developing training materials, responding to investigators, supporting IBC meetings, and completing expanded reporting requirements.

For example, reviewing and posting a publicly releasable incident report is not simply an administrative upload task. It may require consultation with legal counsel, privacy review, security review, redaction of sensitive information, quality assurance review, document management, and long-term record retention. These activities consume time from the same limited staff responsible for direct biosafety oversight.

Similarly, implementation may require reassessment of large numbers of active protocols. At previous institutions where I have worked, implementation of a framework of this scope would likely have required review of hundreds of active protocols, creation of new tracking mechanisms, and significant staff effort that would otherwise have been devoted to protocol review, laboratory inspections, investigator support, training, and incident response.

Why This Matters
The most effective biosafety activities are often the least visible administrative functions.
Safety is improved when biosafety professionals spend time:
• Working directly with investigators;
• Conducting laboratory visits;
• Providing protocol consultations;
• Performing risk assessments;
• Training laboratory personnel;
• Investigating incidents; and
• Identifying hazards before incidents occur.
If implementation results in significant shifts of time toward administrative compliance activities,

institutions may successfully complete paperwork while having less capacity available for direct risk-reduction activities.
The practical question is not whether institutions can eventually comply. Most institutions will make every effort to do so.
The question is whether compliance will require diverting limited resources away from activities that directly support safe science.

Recommendation
NIH should consider:
1. Conducting a formal implementation burden assessment.
2. Providing estimates of anticipated staffing and infrastructure requirements.
3. Developing centralized national reporting and document-management tools.
4. Providing model templates, training resources, and implementation toolkits.
5. Considering implementation supplements or funding opportunities to support compliance activities.
6. Scaling certain requirements based upon institutional size, complexity, and research portfolio.

Modernization is an important and worthwhile goal. However, successful implementation will depend not only on what institutions are required to do, but also on whether they have the resources necessary to do it effectively. The final policy should seek to improve biosafety outcomes while ensuring that limited biosafety resources remain focused on activities that most directly reduce risk and support safe research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

421. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

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We support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

1. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate

director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

2. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety

program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and

near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

3. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

4. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

5. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request.

Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

6. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

7. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

422. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Six-Month Implementation Timeline Is Unrealistic

Observation
I appreciate NIH's desire to implement the proposed biosafety framework promptly and establish consistency across the research enterprise. However, the proposed six-month implementation timeline does not appear to fully account for the breadth of operational changes that institutions will need to make before compliance can reasonably be achieved.

The proposed policy introduces new requirements related to Biosafety Assurances, public transparency, protocol review processes, training, incident reporting, record retention, public posting, and governance structures. Many of these requirements will require institutions to develop entirely new processes and infrastructure.

Real-World Implementation Impact
In a real research environment, implementation involves far more than updating a policy document. Before the effective date, institutions will likely need to:
• Revise institutional policies and procedures;
• Develop Biosafety Assurance processes;
• Create or update public-facing websites;

• Establish records-management and redaction workflows;
• Modify protocol management systems;
• Create new investigator guidance;
• Develop training materials;
• Expand protocol inventories;
• Train IBC members, investigators, biosafety staff, administrators, and institutional officials; and
• Establish workflows for incident review and public reporting.

At many institutions, these changes cannot be completed by a single individual or office. They frequently require coordination among biosafety programs, research administration, information technology offices, legal counsel, communications staff, occupational health programs, compliance offices, and senior leadership.
Many institutions are still evaluating what the policy requires. In several areas, implementation guidance, examples, and operational definitions remain unavailable.

Why This Matters
A compressed implementation period is likely to produce inconsistent implementation across institutions.
Some institutions may interpret requirements conservatively and dramatically expand oversight activities. Others may delay implementation while awaiting guidance. Still others may continue existing oversight practices while attempting to determine how the new framework applies to ongoing research. The result may be variability in compliance rather than consistency.

Recommendation
NIH should consider:
1. Extending the implementation period to at least 24-36 months. The example set by the NIH NSPM-33 Research Security Program roll out is a more realistic model: where input from the regulated community helped shape the final policy and implementation approach, and the carefully planned phased rollout (2024 – present; 2027) has given institutions ample time to prepare and comply.
2. Creating phased implementation milestones.
3. Releasing implementation guidance before the compliance deadline (expected by year end 2026).
4. Providing model policies, templates, and examples.
5. Allowing a transition period during which institutions may continue operating under existing oversight structures while implementing new requirements.
A successful biosafety framework will depend not only on what is required but also on whether institutions are given sufficient time to implement those requirements consistently.

423. Rebecca Moritz

I am responding: On behalf of myself

Name: Rebecca Moritz

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety and Biosecurity Practitioner

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached letter

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached letter

3. Continued utility of Risk Groups: See attached letter

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attached letter

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached letter

6. Other feedback relevant to this resource: See attached letter

Description: rlmoritz5@gmail.com

424. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Biosafety Assurance Approval Requirements Could Unintentionally Disrupt Ongoing Research

Observation
The draft policy appears to require NIH approval of a Biosafety Assurance before covered research may be conducted.
While institutional assurances can be an effective mechanism for establishing accountability, the draft does not clearly address how assurance review timelines will interact with ongoing research activities.
Real-World Implementation Impact
If implemented as written, institutions may find themselves in a situation where:
• A Biosafety Assurance has been submitted;
• The institution is actively working toward compliance;
• Existing research remains underway; but
• NIH review has not yet been completed.
In a real laboratory, this uncertainty has consequences.
Investigators may be unclear whether ongoing work can continue.
Graduate students, postdoctoral researchers, technicians, and research staff may be uncertain whether experiments should proceed.
Research administrators may be unable to provide definitive guidance regarding compliance status.

Institutions may become reluctant to initiate new projects while awaiting assurance approval.
The issue is especially significant if many institutions submit assurances simultaneously and review timelines extend beyond the implementation deadline.

Why This Matters

Research programs require predictability.
Interruptions, uncertainty, or differing institutional interpretations could affect:

- Research continuity;
- Grant performance;
- Workforce planning;
- Trainee progress; and
- Scientific productivity.

These consequences may occur even at institutions that are making good-faith efforts to comply.

Recommendation

NIH should explicitly establish:

1. Provisional or interim assurance mechanisms.
2. Continued operation while an assurance is under review.
3. Deemed approval provisions after defined review periods.
4. Clear transition language for existing awards and ongoing projects.

The final policy should avoid situations where administrative review timelines unintentionally become barriers to ongoing research.

425. Ericka E. Pearce, MS, CBSP(ABSA)

I am responding: On behalf of myself

Name: Ericka E. Pearce, MS, CBSP(ABSA)

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Policy Requires a Clear Transition Strategy

Observation
The proposed framework represents one of the most significant changes to biosafety oversight in decades. However, the draft provides limited guidance regarding how institutions should transition from existing NIH Guidelines-based programs to the new framework.
Real-World Implementation Impact
In practice, institutions will face numerous operational questions, including:
• Which existing protocols require review under the new policy?
• Which currently exempt activities become subject to oversight?
• Must previously approved projects be re-reviewed?
• How should delegated approvals transition?
• What happens to existing institutional policies and guidance documents?
Different institutions may answer these questions differently.
As a result, the same research activity could be handled differently across institutions during the transition period.

Why This Matters
Implementation periods are often when compliance risks are greatest.

Ambiguity during transition can lead to:
• Delayed studies;
• Duplicate reviews;
• Investigator confusion;
• Administrative burden; and
• Inconsistent oversight outcomes.

Recommendation
NIH should publish a dedicated transition framework that includes:
1. Grandfathering provisions.
2. Transition timelines.
3. Renewal expectations.
4. Examples of common implementation scenarios.
5. Frequently asked questions.
Providing a clear roadmap would improve consistency and reduce unnecessary burden during implementation.

426. A.T. Still University of Health Sciences

I am responding: On behalf of an organization

Name: Clayton Furman

Name of Organization: A.T. Still University of Health Sciences

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Our researchers study a variety of fields related to medicine and medical education, but we are a small institution (private university) and have only BSL-1 / BSL-2 labs, so a lot of our interest in this matter related to how such operations may be regulated.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy seems to be well-intended, but there is concern about the scope and reach of some parts of it. The idea that any research agency receiving NIH funding for any project would be subject to NIH regulations for ALL projects being conducted by that entity seems to overstep the reasonable authority of the NIH. Taken to the next logical step, hypothetically, how would this work if all sources of funding implemented similarly broad policies? Suppose, for example, that there is a research lab at a university that receives NIH funding and another lab (or perhaps 20 others) at the same university primarily funding from another source (or other sources). If each funding source were to arbitrarily demand control over how the university conducts all of its research, regardless of funding source, and those requirements were to conflict with one another, that university would be forces to cut ties with one or more sources of funding in order to comply with NIH requirements or vice-versa. Overall, this can only be detrimental to the research, so we do not believe it is fair or reasonable that NIH should make such a demand. Asking that projects directly funding by NIH be conducted in accordance with NIH policy is, of course, a reasonable condition for receiving NIH funding; forcing all projects to comply with NIH rules when NIH doesn't have anything to do with them is not.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Overall, the policy looks to have good intentions and seems to address many of the inconsistencies that might exist within the modern research world. As a smaller entity with only lower-level labs (BSL-1 mostly, and occasionally some BSL-2 work), our principle concern is that the new policy may actually over-stipulate details regarding the composition of an IBC. Put simply, while the objective is on-point, the implementation may not be practical for smaller research entities. It is likely to create an excessive administrative (and potentially financial) burden to maintain a committee with such specific composition when the research being conducted doesn't really justify so much overhead or oversight. It seems as if maybe that part of the policy was written with BSL-3 and BSL-4 labs in mind, and for those applications, it would make sense; the problem is that the exact language in the policy does not allow the IBC to be scaled

appropriately for cases where that level simply isn't necessary. This would be burdensome for an entity of our size and might completely put a small independent lab out of business.

3. Continued utility of Risk Groups: We have not had any issue with nor found any deficiency in the existing system using BSL as per BMBL, so in our experience, there is no practical need to modify this system. The existing BSL system has been in place for years, and I think it would be fair to say that virtually all existing and currently operating laboratories working in related fields are configured to comply with that system. Changing it without a very serious reason would only create more expense and administrative burden for researchers who are already operating on bare minimum resources as it is, in many cases. The idea of designating a risk group based upon specific criteria is sound, but it should only be used as a means of determining what level of biosafety is required, not as a substitute for the existing BSL system.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see the answer to question #1: As it is currently worded, this policy would force compliance with NIH policy upon non-NIH funded projects at any institution receiving NIH funding for any project, and that does not seems fair or reasonable. Publication of "good practices" or the like is a wonderful idea; attempting to force it upon research that is not even supported by NIH in any way can only have detrimental effects to the overall "research industry", making it more difficult to obtain research funding and/or more burdensome to comply with what may or may not even be applicable or worthwhile policies without any provision of resources. What entitles NIH to dictate how a researcher should conduct the work when NIH isn't providing any funding or other resources to support that work? We're all in favor of safety in the lab, but historically, it has never been practical for any organization to issue demands without also issuing resources to enable compliance. In short, if NIH isn't willing to pay the cost of compliance with all of the NIH policies, then NIH doesn't have any right to expect anyone to comply either. As written, the new policy could be interpreted to be retroactively applicable, forcing entities already receiving NIH funding (even if it's only 1% of their total research budget, for example) to have to comply with NIH policy while having no vote on that policy and no additional funding to support compliance provided by NIH. If it's only a small percentage of the overall research budget for a given organization, perhaps the organization may choose to break ties with NIH and ignore the policy entirely, which would not serve NIH or the researcher. If it is a large percentage of a small research organization's budget, that entity may not have the ability to continue functioning without NIH funding and may not really have the resources to comply with NIH policy across the board with other projects, so this effectively borders on being coercive in nature, which is surely not the intention.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: This is bordering on micro-management, honestly. If NIH wants to set forth specific requirements for reporting, etc. as a requirement for obtaining and renewing NIH funding, then that is their prerogative, but it does not seem practical or reasonable for a high-level organization such as NIH to have any need (nevermind the actual practical resources) to manage such details as how individual research organizations keep their meeting minutes. Surely, NIH resources could be put to better use elsewhere. If there is not actually any intention to review or manage the minutia, then it makes no sense to regulate it either, so either way, this seems like a detail that might be too small to really be worth of inclusion in such a policy.

6. Other feedback relevant to this resource: Overall, the policy is good -- it has two primary flaws, for lack of a better term. First, the language granting NIH the authority to mandate compliance across all projects operated by anyone who receives NIH funding for any project needs to be removed -- no organization has the right to arbitrarily give itself authority over tasks in which that organization is not directly involved, and NIH is no exception. Requiring compliance for NIH-funded projects is fine, provided the recipient of NIH funding consents to that requirement before receiving the money. Any attempt to change the arrangement after the money has already been granted is inappropriate, and as written, this language would allow exactly that.

The second area that needs work is the overly detailed establishment and maintenance of IBCs. The idea of having such a committee is a good one; going so far as to micro-manage exactly who should be on the committee and how they should keep minutes is not. An internal committee appropriate to the size of the institution and the scope of the research is a great idea, but as it is currently specified, the committee could potentially cost more in terms of both time and money than the research itself for smaller research entities and is plain and simply not necessary for lower-level biosafety threats such as those typically handled at BSL-1 and BSL-2 facilities. As written, the precise details of how the IBC must be constituted, etc. would seem applicable for only BSL-3 and higher, so it needs to be revamped to permit reasonable scaling for labs where the biohazards simply do not justify that degree of oversight and over-management.

Once those two issues are fixed, the rest seems to be a step in the right direction -- thank you for all the hard work and your continued support of scientific research!

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Description: This is the official response from ATSU, as agreed upon by our own internal review boards and experts, approved by university leadership. The responses to the questions above are largely the same idea but without institutional review, so this document should be taken as our official response.

RE: Notice NOT-OD-26-112 — Public Comment on Draft Biosafety Oversight Policy Framework

To Whom It May Concern:

We appreciate the opportunity to comment on NOT-OD-26-112. We fully support the NIH's commitment to biosafety. We write to offer targeted recommendations regarding administrative harmonization for co-regulated entities and scalability for committee composition requirements.

1. Regulatory Harmonization and Administrative Efficiency

We strongly support the provision in Section II allowing research subject to this Policy to proceed under the primary oversight of another federal agency once applicable clearances are obtained. This deference prevents duplicate regulatory burdens for co-regulated facilities.

To ensure this principle translates effectively into practice across all institutional operations, we request that the final policy address a key operational inefficiency:

- **Streamlined Incident & Administrative Reporting**: Where an incident or protocol is already subject to reporting under another federal agency, permit institutions to submit copies of primary agency filings to fulfill NIH reporting requirements, avoiding redundant multi-part documentation.

2. Scalability of Committee Structure for Smaller Entities and Low-Risk Work

We applaud the NIH for introducing "delegated review" in Section IV for lower-risk (Category C) research, recognizing that routine protocol reviews do not require the administrative weight of a convened full committee. However, a significant operational disconnect remains between protocol review workflows and institutional roster mandates.

While lower-risk protocols can be cleared by a single designated reviewer, Section III-B still requires every grantee institution to recruit, onboard, and maintain a standing 5-member Institutional Biosafety Committee–including two non-affiliated community members and specialized technical experts. For smaller institutions, single-lab operations, or facilities conducting exclusively low-risk research, maintaining a standing 5-member panel solely for roster compliance presents an unnecessary administrative burden.

To align governance structure with protocol risk, we request:

- **Shared and Regional IBC Pathways**: Explicitly permit smaller or lower-risk entities to fulfill Section III-B committee requirements by utilizing an established regional, shared, or centralized IBC rather than mandating an independent standing committee at every physical grantee site.

- **Conditional Committee Composition**: Clarify that specialized technical expertise (e.g., plant or animal containment specialists) and expanded committee sizes are required conditionally based on active research modalities, allowing institutions conducting standard bench research to maintain a proportional standing committee with ad-hoc technical consultants engaged as needed.

Tailoring administrative requirements to fit the scale, risk profile, and funding structures of research entities will improve overall institutional compliance without placing undue burdens on smaller institutions.

Thank you for your consideration of these recommendations.

427. Leyma De Haro

I am responding: On behalf of myself

Name: Leyma De Haro

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support NIH's proposal to expand biosafety oversight beyond research involving recombinant or synthetic nucleic acid molecules. This is an important modernization of the current framework. However, the proposed policy should more explicitly address emerging technologies that challenge conventional definitions of biological hazards and established risk assessment methodologies.

I recommend that NIH consider the following areas:
1. Mirror life and mirror-image biological systems. The policy does not explicitly address mirror life. Although hypothetical self-replicating mirror organisms could fall within the definition of novel organisms, their potential biological and ecological hazards may not be adequately characterized using conventional risk assessment approaches. NIH should distinguish between research involving nonreplicating mirror-image biomolecules, which have legitimate scientific and therapeutic applications, and research directed toward creating self-replicating mirror organisms, which warrants specialized precautionary oversight.

2. AI-designed biological systems. I welcome the explicit recognition of artificial intelligence (AI) in the proposed definition of novel agents or organisms. However, this definition should also account for AI-designed proteins, genetic circuits, synthetic genomes, and other de novo biological systems that may lack recognizable natural counterparts. Risk assessment should consider biological function, phenotype, potential emergent properties, and scientific uncertainty, rather than relying primarily on parental organisms or the origins of genetic sequences.

3. Autonomous and AI-directed laboratories. The policy should explicitly address biological research conducted through automated and self-driving laboratories. These systems may autonomously select experiments, modify parameters, and execute laboratory procedures. NIH should clarify when activities conducted by such systems fall within an existing institutional approval and when modifications require renewed risk assessment or IBC review.

4. Cyberbiosecurity. Modern biological research increasingly depends on digital infrastructure, including AI systems, electronic research protocols, laboratory information management systems, and automated instrumentation. Compromise of these systems can create physical biosafety and biosecurity risks. NIH should explicitly recognize cyberbiosecurity vulnerabilities when they could affect biological containment, experimental integrity, or safe laboratory operations.

5. Environmental and ecological risks. The definition of biohazards emphasizes human health. NIH should clarify whether and how the policy addresses engineered biological systems that may present significant ecological or environmental hazards without necessarily posing direct pathogenic risks to humans.

Overall, I recommend that NIH adopt a technology-neutral, risk-based approach that considers not only the intrinsic hazards of biological agents but also their functions, experimental applications, interactions with other systems, and associated uncertainties. The policy should remain sufficiently flexible to accommodate future developments in synthetic biology, AI, and laboratory automation, while avoiding unnecessary restrictions on well-characterized, low-risk research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I support NIH's proposed tiered oversight framework, provided that oversight responsibilities are proportionate to the risks, complexity, and scientific uncertainties associated with the research. A risk-based approach should preserve institutional flexibility for routine, well-characterized research while ensuring that activities involving novel or potentially consequential biological hazards receive appropriate scrutiny.

I recommend that NIH consider the following:
1. Clear criteria for federal versus institutional oversight. NIH should establish consistent, scientifically justified criteria for determining which research activities require federal review and which can be managed through Institutional Biosafety Committees (IBCs). Federal oversight should focus on activities presenting significant or poorly characterized hazards, particularly when risks may extend beyond the institution conducting the research. Local oversight should remain the primary mechanism for activities involving established hazards and validated containment practices.

2. Oversight of emerging technologies. Research involving AI-designed biological systems, novel synthetic organisms, and potentially self-replicating mirror biological systems may introduce uncertainties that are not adequately captured by conventional Risk Group classifications. NIH should establish clear escalation criteria for research involving biological systems with potentially significant but poorly characterized hazards. Such criteria should be based on the properties and risks of the proposed research, rather than the mere use of an emerging technology.

3. Adaptive oversight of autonomous laboratories. AI-directed and self-driving laboratories may modify experimental parameters or select subsequent experiments without direct human intervention at every step. NIH should consider an oversight model in which institutions approve a defined experimental operating envelope. Activities conducted within that envelope could proceed under existing approval, while modifications introducing new hazards or materially changing the original risk assessment would require renewed review. This would support innovation while maintaining appropriate human accountability.

4. Strengthening IBC technical expertise. The increasing complexity of synthetic biology and AI-enabled research may exceed the specialized expertise available within individual IBCs. NIH should encourage access to external subject-matter experts, shared institutional resources, and specialized training in emerging biological technologies. Institutions should not necessarily be required to maintain permanent expertise in every emerging field, provided they can obtain qualified independent review when needed.

5. Consistency without unnecessary administrative burden. Institutions may interpret similar research activities differently, resulting in inconsistent containment requirements or oversight decisions. NIH should provide standardized risk assessment methodologies, decision-support tools, and clear criteria for delegated review. AI-assisted tools could help investigators and IBCs identify relevant hazards, review scientific evidence, and document assessments. However, final decisions should remain with qualified human reviewers.

6. Periodic reassessment based on emerging evidence. Oversight classifications should be revisited when new scientific findings materially change the understanding of a biological system's hazards or when experimental activities change. NIH should provide guidance on reassessment triggers rather than relying exclusively on fixed review intervals.

Overall, I recommend a framework in which institutional oversight remains the foundation of routine biosafety governance, while federal oversight provides consistency, specialized expertise, and additional review for research presenting substantial or poorly characterized risks. Importantly, the level of oversight should be determined by the actual hazards and uncertainties of the proposed work, not simply by the novelty of the technology being used.

3. Continued utility of Risk Groups: I support the continued use of Risk Groups (RGs) as a baseline for biological risk assessment. RG classifications provide a useful starting point for identifying the established hazards associated with biological agents. However, additional clarification, standardized guidance, and practical training are needed to ensure that RGs are interpreted and applied consistently, particularly when biological agents are genetically modified.

Risk Groups and Biosafety Levels (BSLs) serve distinct but complementary purposes. RG classifications characterize the hazards associated with biological agents, whereas BSLs describe the laboratory practices, safety equipment, and facility safeguards needed to conduct specific activities safely. An agent's Risk Group should inform, but should not automatically determine, the appropriate Biosafety Level. The final containment determination should result from a comprehensive, activity-specific risk assessment.

I recommend that NIH address the following:
1. Clarify the relationship between RGs and BSLs. NIH should provide explicit guidance explaining how RG classifications inform containment decisions without establishing an automatic correspondence between RG and BSL numbers. Practical examples would help investigators and IBCs understand when the appropriate containment level may differ from the agent's Risk Group.

2. Provide guidance for genetically modified and synthetic biological agents. Genetic modifications can alter an agent's characteristics, including pathogenicity, host range, transmissibility, environmental

stability, and other relevant biological properties. NIH should clarify how these changes should be evaluated when determining whether an existing RG classification remains appropriate. This guidance should also address novel synthetic biological systems for which conventional RG classifications may have limited applicability.

3. Standardize risk assessment training. NIH should develop practical training materials for principal investigators, biosafety professionals, and IBC members. Training should emphasize the distinction between agent hazards and activity-specific risks, the selection of appropriate containment measures, and the evaluation of genetic modifications. Case studies involving conventional pathogens, engineered organisms, and emerging biotechnologies would be particularly valuable.

4. Promote consistency across institutions. Different institutions may reach different containment decisions for comparable research activities. Although some variation is justified by differences in facilities, procedures, and institutional capabilities, NIH should provide standardized risk assessment templates, decision-support guidance, and illustrative examples to reduce inconsistencies arising from misinterpretation of RG classifications.

5. Clarify the relationship with the BMBL. NIH should ensure that its guidance is consistent with the risk assessment principles outlined in Biosafety in Microbiological and Biomedical Laboratories (BMBL). Clear cross-references would help institutions apply both documents appropriately and avoid confusion regarding their respective purposes.

Overall, I recommend retaining Risk Groups as a foundational component of biosafety risk assessment while strengthening guidance on their interpretation and limitations. The priority should be to improve the quality and consistency of risk assessments through clear definitions, practical examples, and standardized training, rather than replacing RG classifications with BSL designations.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I support expanding the scope of biosafety oversight beyond NIH-funded institutions rather than relying primarily on voluntary compliance. Biological hazards do not depend on an institution's funding source, and the potential consequences of inadequate biosafety practices can extend beyond laboratory personnel to surrounding communities and the environment.

The discovery of an unauthorized biological laboratory in Reedley, California, in 2023 demonstrated significant weaknesses in the existing regulatory and oversight framework. This incident raised serious questions about how laboratories handling potentially hazardous biological materials can operate outside established institutional biosafety programs and how federal, state, and local authorities coordinate oversight and enforcement.

Voluntary compliance alone is insufficient to address these vulnerabilities. Institutions that already prioritize biosafety are more likely to adopt voluntary standards, while laboratories with inadequate expertise, poor safety practices, or deliberate disregard for regulatory requirements may remain outside the oversight system.

I recommend that NIH consider the following:

1. Expand the applicability of biosafety oversight. NIH should work with other federal agencies and relevant state authorities to develop a framework establishing minimum biosafety requirements for laboratories conducting research with potentially hazardous biological agents, regardless of whether they receive NIH funding. Any expansion beyond NIH's current authority should be supported by appropriate regulatory or legislative mechanisms.

2. Establish minimum institutional biosafety requirements. Laboratories conducting covered biological research should be required to demonstrate appropriate risk assessments, qualified biosafety oversight, personnel training, containment practices, biological material management, and emergency response procedures. Requirements should remain proportionate to the hazards and activities involved.

3. Strengthen laboratory accountability and regulatory coordination. Federal, state, and local authorities should have clearly defined responsibilities for identifying and responding to laboratories conducting potentially hazardous biological activities without appropriate oversight. Mechanisms for information sharing, inspections, and enforcement should be strengthened to prevent regulatory gaps.

4. Require qualified biosafety expertise. Biosafety assessments and oversight of hazardous biological research should be performed or reviewed by appropriately qualified professionals. Self-assessment tools and general educational resources may support compliance, but they should not substitute for competent biosafety review or independent oversight when the risks warrant it.

5. Establish mechanisms for identifying laboratories operating outside established oversight systems. NIH should collaborate with relevant regulatory agencies to explore proportionate laboratory registration, notification, or licensing requirements for research involving specified biological hazards. These mechanisms should help authorities identify facilities conducting covered activities and verify that appropriate biosafety protections are in place.

6. Preserve risk-based proportionality. Expanded oversight should not impose unnecessary requirements on routine, low-risk biological activities. Oversight requirements should be based on the actual hazards, experimental activities, and potential consequences of laboratory operations rather than institutional affiliation or funding status.

I recommend that NIH move beyond encouraging voluntary compliance and support the development of a coordinated national framework for biosafety oversight. The objective should be to ensure that laboratories conducting potentially hazardous biological research are subject to appropriate minimum safety standards, qualified oversight, and enforceable accountability mechanisms, regardless of their funding source.

The Reedley laboratory incident demonstrates the potential consequences of regulatory gaps. A modernized national biosafety framework should seek to prevent similar situations rather than rely on voluntary participation by institutions that may lack the expertise, resources, or willingness to establish adequate biosafety practices.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Modernize biosafety incident reporting through a centralized, web-based information system.
I strongly recommend that NIH move beyond PDF-based incident reporting and establish a secure, centralized online reporting system. Although standardized PDF templates may improve consistency in documentation, they are not an optimal mechanism for collecting, managing, aggregating, and analyzing incident data across institutions.

The proposed National Biosafety Data and Safety Analysis Center (NBDSAC) represents an important opportunity to modernize biosafety surveillance and establish a national evidence base for laboratory safety. However, realizing this potential will require structured, interoperable, machine-readable data rather than relying primarily on individual PDF submissions.

An online reporting system should incorporate the following capabilities:

1. Structured electronic reporting: Standardized fields, controlled terminology, and appropriate validation rules to facilitate consistent data collection and reduce incomplete or incompatible submissions.

2. Incident tracking and follow-up: Unique incident identifiers, submission histories, investigation updates, corrective-action tracking, and mechanisms for documenting the effectiveness of preventive interventions.

3. Data aggregation and trend analysis: The ability to analyze incidents and near misses across institutions, biological agents, experimental activities, equipment types, contributing factors, and time periods. Such analyses should account for differences in institutional reporting practices and laboratory activities.

4. Integration with institutional systems: Secure interfaces and standardized data formats that allow institutions to submit information from existing environmental health and safety, incident management, and laboratory information systems without unnecessary duplication of effort.

5. Data security and confidentiality: Role-based access controls, encryption, appropriate de-identification, and clear data governance policies to protect confidential research, personnel information, and security-sensitive laboratory details.

6. Analytical and AI-assisted capabilities: A properly structured database could eventually support advanced statistical analyses, machine learning, and AI-assisted identification of recurring failure mechanisms and emerging biosafety risks. Such applications should be scientifically validated and subject to appropriate human oversight.

7. Institutional feedback and benchmarking: Participating institutions should be able to access their own incident histories, track corrective actions, and receive aggregated national findings and lessons learned. Any benchmarking should account for differences in reporting culture, institutional research activities, and exposure opportunities.

NIH could retain downloadable PDF templates as supplementary resources or temporary alternatives during implementation. However, they should not become the primary long-term mechanism for national biosafety incident reporting. I encourage NIH to design the reporting platform in coordination with the proposed NBDSAC, biosafety professionals, institutional reporting personnel, and relevant federal agencies. The system should support both regulatory reporting and scientific analysis while minimizing administrative burden.

The objective should not simply be to digitize a form. It should be to establish a modern national biosafety information system capable of transforming incident reports into actionable knowledge that improves laboratory safety and prevents future incidents.

6. Other feedback relevant to this resource: I support NIH's plan to develop supplemental implementation resources. These materials will be essential to ensuring consistent interpretation and application of the revised policy across institutions.

I recommend prioritizing the following areas:
1. Risk Group (RG) classifications and Biosafety Level (BSL) determinations. Provide clear guidance on the distinction between RGs and BSLs, particularly when biological agents are genetically modified. Practical examples should illustrate how agent characteristics, experimental procedures, and available containment measures inform the final biosafety assessment. Standardized training materials for investigators, biosafety professionals, and IBC members would improve consistency across institutions.

2. IBC review and oversight procedures. Provide examples clarifying which research activities require full IBC review, which qualify for delegated review, and which changes to approved protocols require reassessment. Guidance should also explain when institutions must consult NIH regarding novel or emerging agents for which established containment recommendations are unavailable.

3. Incident reporting and documentation. Provide guidance distinguishing initial incident notifications from final investigation reports, including expectations for root cause analysis, corrective actions, and verification of their effectiveness. I strongly recommend replacing PDF-based reporting as the primary submission mechanism with a secure, structured online reporting system. Such a system would facilitate tracking, consistency, data aggregation, and trend analysis, particularly in support of the proposed National Biosafety Data and Safety Analysis Center (NBDSAC).

4. Implementation examples and training. Provide practical case studies and completed examples of risk assessments, IBC documentation, and incident investigations. These resources would be particularly valuable during the transition from the current NIH Guidelines to the proposed policy.

Overall, implementation resources should focus on clarifying policy requirements, supporting consistent institutional decisions, and reducing unnecessary administrative burden. They should complement, rather than replace, the professional judgment of qualified biosafety personnel.

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Leyma P. De Haro, Ph.D., RBP (ABSA)

Biomedical scientist | Biorisk management and emerging biotechnology governance | deharolp@gmail.com

October 19, 2026

To: National Institutes of Health, Office of Science Policy

Re: Public comments on NOT-OD-26-112 — Draft NIH Biosafety Policy for Research Involving Biohazards

Dear NIH Office of Science Policy:

I am submitting the attached comments in my individual professional capacity to support the development of a scientifically grounded, practical, and forward-looking NIH biosafety framework. I am a biomedical scientist with a Ph.D. in molecular genetics and microbiology and extensive experience in biosafety, biosecurity, institutional risk assessment, high-containment laboratories, and Institutional Biosafety Committee oversight. My professional work has included research universities, national laboratories, public-health laboratories, and international biorisk management activities.

My scholarship focuses in part on emerging biological technologies and their governance. I am the author of Biosecurity in the Age of Synthetic Biology (CRC Press, 2024). My publications include “Biosecurity Risk Assessment for the Use of Artificial Intelligence in Synthetic Biology” (Applied Biosafety, 2024) and “Using Embodied AI Agents to Automate Biorisk Management Tasks in High-Containment Laboratories” (Applied Biosafety, 2025).

I participated in the February 2025 Spirit of Asilomar and the Future of Biotechnology summit, convened on the 50th anniversary of the original Asilomar meeting. Following the summit, I coauthored “The Spirit of Asilomar: Lessons for the Next Era of Biotechnology Governance” (Trends in Biotechnology, 2025; DOI: 10.1016/j.tibtech.2025.05.013). I also endorsed several of the summit’s published entreaties, including “The Importance of Redlines in the Life Sciences,” “Condemning & Making Obsolete Biological Weapons,” “Safeguarding the Benefits of Synthetic Cell Engineering,” and “A Statement of Shared Stewardship.” These entreaties express the views of their respective authors and endorsers; they are not consensus statements of all conference participants.

I welcome NIH’s effort to move beyond a framework centered on recombinant and synthetic nucleic acids toward broader, risk-based biosafety oversight. The attached comments focus on issues likely to become increasingly consequential: AI-designed and novel synthetic biological systems, mirror-image biology, autonomous experimentation, AI-assisted risk assessment, cyberbiosecurity, biosafety incident-data infrastructure, and clear institutional oversight responsibilities. These recommendations are intended to strengthen biosafety without unduly constraining beneficial scientific research.

Thank you for considering these comments as NIH develops the final policy.

Sincerely,

Leyma P. De Haro, Ph.D., RBP (ABSA)

Submitted in an individual professional capacity

Selected supporting references: Molla et al., Trends in Biotechnology 43(8):1809–1812 (2025), doi:10.1016/j.tibtech.2025.05.013; Spirit of Asilomar entreaties, Rice University repository: https://repository.rice.edu/collections/e4e3a33e-08a4-427a-9b59-cb30d93b8bbe

Summary of Comments on the Draft NIH Biosafety Policy

NIH Notice NOT-OD-26-112 | Draft policy for research involving biohazards | October 19, 2026

Purpose. This working summary identifies recommendations for strengthening the proposed policy with respect to emerging biotechnology, institutional oversight, and practical implementation. These are proposed comments, not requirements already established by NIH.

1. Address mirror life explicitly

Priority: High | Relevant draft sections: Sections II, IV-1, V-A, V-C

Clarify whether wholly or partially mirror-image biological systems fall within the definition of a biohazard or novel organism. Distinguish useful research on nonreplicating mirror-image molecules from work toward self-replicating mirror organisms. Provide a precautionary referral and assessment pathway for the latter, addressing uncertainty about biological interactions, environmental persistence, detection, and effective containment. Avoid assigning conventional Risk Groups without adequate evidence.

2. Modernize assessment of AI-designed and de novo biological systems

Priority: High | Relevant draft sections: Sections II, V-B, V-C

Explicitly address AI-designed proteins, genetic circuits, and organisms with no meaningful parental organism. Supplement sequence provenance and parental Risk Group considerations with functional, phenotype-based, context-dependent, and uncertainty-aware assessment. Treat lack of an identified hazardous parent as insufficient evidence of safety.

3. Define oversight for autonomous and AI-directed experiments

Priority: High | Relevant draft sections: Sections III-B, III-C, V-D, V-E

Specify how IBC-approved research applies when an automated or AI-driven system changes experimental parameters or selects subsequent experiments. Encourage defined, validated operating envelopes, pre-established escalation triggers, audit trails, safeguards against out-of-scope operations, and human authority to intervene. Require renewed review when changes materially alter risk.

4. Enable validated AI-assisted biosafety risk assessment

Priority: High | Relevant draft sections: Sections III-B, III-C, V

Recognize computational decision-support tools for literature synthesis, protocol triage, identification of missing hazard information, and documentation. Make clear that IBCs and investigators retain decision authority. Provide guidance on tool validation, evidence traceability, accuracy, uncertainty, confidentiality, and periodic reevaluation.

5. Build the National Biosafety Data and Safety Analysis Center as a scientific resource

Priority: High | Relevant draft sections: Sections II, III-C, III-D

Support the proposed center and develop standardized, interoperable incident and near-miss data fields, including exposure context, causal factors, process and equipment conditions, and corrective actions. Enable rigorous trend analysis while protecting confidentiality and guarding against re-identification. Account for reporting-culture differences before making comparisons among institutions.

6. Integrate cyberbiosecurity where digital compromise creates biological risk

Priority: High | Relevant draft sections: Sections III-A, III-B, V-D, V-E

Include proportionate evaluation of connected instruments, automated systems, electronic protocols, biological inventories, laboratory information systems, and facility controls. Clarify coordination with institutional cybersecurity teams, and when a digital incident that affects containment or safe experimental operation warrants biosafety investigation or reporting.

7. Clarify boundaries of biosafety, biosecurity, and dual-use oversight

Priority: Medium | Relevant draft sections: Sections II, III-B, IV

Explain referral and coordination mechanisms among IBCs, institutional research security functions, and applicable federal oversight frameworks. Do not imply that IBCs alone should adjudicate all dual-use or information-security issues. Avoid duplicate reviews and conflicting determinations.

8. Strengthen institutional implementation and proportional oversight

Priority: Medium | Relevant draft sections: Sections II, III-A, III-B, IV

Provide actionable criteria for delegated review and for determining when a protocol change requires reassessment. Evaluate the net workload associated with expanded coverage, Biosafety Assurances, three-year de novo reviews, incident reporting, and public posting. Supply standardized templates, training, transition support, and realistic workload assumptions.

9. Balance transparency with protection of sensitive information

Priority: Medium | Relevant draft sections: Sections III-A, III-B

Clarify redaction criteria for IBC minutes and incident reports. Protect confidential research details, individual privacy, physical security vulnerabilities, and sensitive operational information while ensuring meaningful public accountability. Provide consistent examples and a process for resolving disclosure disagreements.

10. Clarify environmental and nonhuman risk boundaries

Priority: Medium | Relevant draft sections: Sections II, V-A, V-B, V-E

Resolve the tension between a scope centered on human health and risk assessments that also consider ecological and nonhuman impacts. Explain handling of gene-drive systems and other novel synthetic organisms for which environmental effects may be central, including where field-release activities fall outside this laboratory-focused policy.

Overall recommendation

Retain the proposed expansion from recombinant-DNA-focused guidance to risk-based oversight of biohazards. Strengthen it with forward-looking provisions for novel biological architectures, AI-enabled design and experimentation, and digitally connected laboratories. Pair these provisions with scientifically grounded, proportionate review procedures and a national learning system for biosafety incidents and near misses.

Primary sources

NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026). https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

NIH Office of Science Policy, public comment form: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

Submission note: NIH lists October 19, 2026 as the response deadline and advises against including information that should not be made public.

428. University of Michigan

I am responding: On behalf of an organization

Name: William Greer

Name of Organization: University of Michigan

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: 1. Purpose and program identity - Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation - Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.
Requests for consideration. Identify activities requiring no submission or review, documentation only, or

prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

3. Institutional accountability and Biosafety Assurances - Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.
Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.
Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

4. IBC establishment functions and operations - Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.
Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language. The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.
Experienced program leadership and the Biological Safety Officer
The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.
Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting - Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.
Clinical activities and oversight endpoints
Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.
Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.
Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest
The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.
Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

6. NIH review and containment determinations - Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

7. IBC review pathways and clinical oversight - Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.
Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.
Proposed designated member review procedure
Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.
If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer the submission to the full committee for review. Multiple reviewers must agree; unresolved differences shall go to the full committee.
Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

3. Continued utility of Risk Groups: 8. Risk assessment and specialized materials - Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.
Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

6. Other feedback relevant to this resource: Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.
Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specifically define the required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.
Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

9. NIH implementation responsibilities and coordination - Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

Uploaded File: University-of-Michigan-Comments_NIH_Biohazards_Policy.docx

Community Comments on the Draft NIH Biosafety Policy

Recommendations to the National Institutes of Health Office of Science Policy

The University of Michigan supports the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. The comments presented summarize the University's detailed discussions, comments, and priority requests and follow the draft policy's section order.

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

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Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

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3. Institutional accountability and Biosafety Assurances

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Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specifically define the required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

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4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

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Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.

Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving

Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer the submission to the full committee for review. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

Policy source

Draft NIH Biosafety Policy for Research Involving Biohazards, NIH Notice NOT-OD-26-112, released August 19, 2026. Section references throughout refer to this draft.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

429. Rob Foreman

I am responding: On behalf of myself

Name: Rob Foreman

Name of Organization: Northwestern University

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attached document.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see attached document.

3. Continued utility of Risk Groups: Please see attached document.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see attached document.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attached document.

6. Other feedback relevant to this resource: Please see attached document.

Uploaded File: Response-Draft-NIH-Biosafety-Policy.pdf

Description: The attached document provides a thorough response to all areas listed above.

The Draft NIH Biosafety Policy for Research Involving Biohazards (the Policy) is intended to be an update to the existing NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines). However, the result is a policy that presents a confusing mixture of incomplete rules that ignores many key features of the NIH Guidelines that were crafted and refined over decades of consideration and interpretation. The new policy was an attempt to streamline the oversight of the Institutional Biosafety Committee (IBC) and provide more authority. Unfortunately, the ambiguity and lack of examples create greater confusion where little to none had existed.

The Policy shifts the focus of its oversight to human-centric pathogens in a way that ignores the potential negative economic and societal outcomes of pathogens that infect animals and plants. While the Policy states that pathogens infecting animals and plants will be addressed by policies from other agencies, the lack of such policies is very notable and concerning. It is strongly recommended that the Policy reconsider the absence of animal and plant pathogens that do not infect humans to ensure appropriate and consistent oversight is provided.

The Policy sets forth an extremely aggressive timeline for implementation and compliance. Institutions will have six months from Policy publication to implement all changes. The Policy fails to provide a framework for how ongoing basic sciences research and clinical research that is subject to the NIH Guidelines will be impacted. For example: will review/approval of research by the IBC be halted pending acceptance of the institutions AOR assurance by the NIH? Moreover, guidance will necessarily change for how institutions will handle HGT studies (which are not directly referenced or redefined in the Policy) and how IBCs are expected to work with the local Institutional Review Board (IRB)

Compliance with this policy will require changes in institutional policy, training materials, printed materials, and significant changes to oversight systems. Electronic systems that are employed to ensure compliance with applicable federal policies are often managed and updated by third-party companies. Institutions will be dependent on the speed with which these companies will be able to complete the necessary changes. Making changes will also be dependent upon accurate interpretation of the Policy, which will likely not be settled by the time it is published. The time and financial costs of making such changes will be significant.

The Policy is also being implemented within a similar timeframe as the United States Government Policy for Stopping High-Risk Life Sciences Research (DGOF Policy). There is a high degree of overlap between these policies but nuanced differences will make implementation of both policies at the same time an incredibly difficult burden on both research professionals and administrative staff. Moreover, the Policy states that institutions must demonstrate compliance within 6 months of implementation but no description of how compliance will be demonstrated.

There are noted gaps within the definitions provided within the Policy that are cause for concern. In particular, the definition of Biological Agent focuses on agents that cause disease in healthy individuals. This definition does not account for microorganisms that are commensal in humans but may exacerbate health conditions if exposure occurs. Agents that cause disease in humans are worth studying, and therefore providing oversight, due to their potential to cause disease in humans if certain conditions are met or fortuitous genetic modifications naturally occur. This definition also does not encompass agents that do not cause disease in humans but enhance the pathogenicity of the bacteria they infect, e.g., phages.

The focus on agents that cause disease in humans is also concerning because the ecosystem is broad and includes animals. Biological agents that are infectious to animals or plants but not humans could have significant societal and economic impacts. Absent guidance from other, relevant agencies, it is unclear how oversight will be provided to these agents.

The definition of toxin is also ambiguous as it does not describe what is meant by harm to a human. Some small proteins, such as allergens, are not toxic but are still capable of causing acute harm or harm following long-term exposure. Overall, the definitions need to be more descriptive and less available for interpretation.

Similar to the definitions section, the roles and responsibilities section, Section III, would greatly benefit from more precise and descriptive language as well as examples of how to implement this policy. Examples should be provided for biosafety assurance, posting minutes, reporting and posting incidents, and specific training requirements. The requirement for a Biosafety Officer (BSO) is also unclear: some sections state that it is required for research at BSL3 and higher while other sections state that a BSO is required for research with organisms that are Risk Group (RG) 3 and higher. These statements are incongruous and conflate Risk Group with Biocontainment Level. Moreover, many responsibilities are assigned to the BSO throughout this policy despite the fact that the position is not formally required in most instances when such work will be conducted (at BSL2 and below). Additional guidance regarding what responsibilities the BSO may delegate and to whom would also be helpful.

This section also states that the NIH must be petitioned to determine the appropriate biocontainment level or reduce the biocontainment level for RG3 and RG4 organisms *each time* a request is made. Lentiviral vectors are ubiquitous in life sciences research despite the parent organism earning a RG3 rating. Nevertheless, these agents are typically handled at BSL2. Will the NIH be providing a blanket downgrading of these agents to BSL2? Will such a request be granted at an institution level? Or would downgrading such organisms require a different request dependent upon transgene?

The role and responsibilities of the Principal Investigator (PI) are also outlined in this section but would benefit from additional clarity. This section states that the PI must initiate the risk assessment process. Guidance for how this should be documented would support this process. The PI is required to submit amendments when biorisk

changes but this section does not provide guidance for how the alteration (or increase) in risk is determined. Lastly, additional guidance regarding the PI's responsibility to submit voluntary safety/near miss information would be appreciated and if this information should be relayed through the BSO and/or the IBC and/or another institutional official.

This section should also provide guidance about how the NIH will assign containment levels for both novel and existing biological agents. There is some information about this process, however, it is buried in four short bullet points at the end of the document and provides insufficient guidance. Additional guidance should also be provided regarding so-called "low" or "high" risk activities. These qualifiers for risk are relative and cannot be consistently applied. Administrative and engineering controls are intended to reduce risk before a researcher even begins work. Thus, risk is inherently lower with well-trained staff and well-appointed facilities. Moreover, some research institutions are more risk-tolerant than others.

The Policy should also consider bringing forward major tenants of the NIH Guidelines that continue to be relevant. For example, the Policy no longer explicitly prohibits cloning of clinically relevant drug selection markers into human pathogens. While this activity would likely be prohibited or heavily regulated by the DGOF Policy, that policy is not directly referenced and should be. Moreover, the structure of the NIH Guidelines that clearly defines categories of research and the approval required for each should be considered for the Policy. These categories for research provide concrete examples for researchers when determining the type of research they are conducting and guidance for biosafety professionals and IBCs when reviewing and approving such research.

While it can be generally agreed upon by biosafety professionals that the NIH Guidelines needed to be reconsidered, one major benefit to the aged document is the iterative process of defining and redefining research categories. This process has occurred throughout the lifetime of the document and is thanks to diligent, considerate, and critical researchers and biosafety professionals. In contrast, this Policy significantly lacks the clarity of research categories that the current NIH Guidelines provides. Each section of research that is covered in Section IV of this document needs to provide concrete examples of the categories to ensure appropriate and consistent application. Consistency of application is of critical importance to ensure overall compliance and reduce confusion among research staff and research programs writ large.

430. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Hematology and iron metabolism

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: In the "General Definitions" section of NOT-OD-26-112, the document describes the transient expression of nucleic acids that “can be transcribed or translated” as a genetic modification. By definition this is incorrect and the transient expression from nucleic acids does not alter or modify the underlying genetics of the organism which hosts it. This definition would greatly impact the use of any transient gene expression system. This would limit the use of plasmid expression systems in yeast, bacteria or mammalian cells, morpholinos in zerba fish, or any mRNA delivery systems based on nanoparticles. All are routinely employed in most molecular laboratories with essentially no risk to researchers or the general public.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

431. Ludovic Desvignes

I am responding: On behalf of myself

Name: Ludovic Desvignes

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious diseases and microbiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The hazard-based scope is the right direction to provide practical and science-based institutional oversight, but the operative sentence is ambiguous: it is not clear whether the “known or potential risk to human health” condition qualifies each of the four enumerated categories or stands as an independent heading. Read the second way, the policy captures every genetically modified laboratory strain and transgenic rodent line. The two readings differ in institutional registration volume by roughly an order of magnitude. No exemption appendix replaces Section III-F and Appendix C. Four definitions over-capture generally low-risk experiments or leaves gaps: genetic modification reaches transient transfection, mRNA delivery, chemical mutagenesis and serial passage; toxin has no potency threshold and, being limited to proteins and peptides, excludes the non-proteinaceous Select Agent toxins the policy cross-references; zoonotic and novel are drafted so broadly that Section IV-1 federal review appears to capture routine work. Inadvertent gaps: large-scale containment (Appendix K) has no successor, leaving pilot-scale and manufacturing work with Risk Group 2 organisms unaddressed; deliberate environmental release is excluded from “laboratory research,” so the gene drive release decision falls outside the framework the policy otherwise builds for gene drives; and plant and arthropod containment (Appendices P and Q) end without replacement. The “institution” is also undefined, which matters for academic medical centers comprising several legal entities. An additional question stems from the statement that "Biological agent inventory and security issues [at BSL-3/ABSL-3] that may have public health consequences" must be reported to the NIH; does this imply that there will be federally mandated material inventories for research at biosafety level 3? And if yes, which will be the agency/mechanisms for oversight?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The three-tier structure is sound in principle; two placements invert it in practice. Primary cells and tissues that may carry adventitious agents are assigned to convened IBC review, moving the highest-volume, lowest-risk activity in an academic medical center into the most resource-intensive tier, while genetically modified Risk Group 1 work receives delegated review. Synthetically generated self-aggregating proteins are likewise placed in convened review alongside infectious prions, with no distinction drawn between them. We recommend moving both to delegated review. The policy also states that it removes administrative burden, but its lowest tier still requires prospective approval: there is no successor to Section III-E

notification or Section III-F exemption, so the total number of approvals rises even before the scope expansion is counted. We recommend restoring a notification tier. At the federal tier, Section IV-1 triggers are unbounded by the zoonotic and novel definitions, and NIH's reciprocal obligation carries no determination deadline, deemed-approval provision, or interim containment pathway. We recommend a 45-day determination with a written interim response, and permission to proceed at the IBC-assessed level where that period lapses and the assessment supports BSL-3 or lower. Criteria are also needed for when a published containment-reduction determination may be relied on, since misjudging equivalence is itself a reportable violation.

3. Continued utility of Risk Groups: Risk Groups remain useful and should be retained, including for genetically modified agents, where the parent agent's classification is the correct starting point for assessing what a modification changes. Risk Groups and Biosafety Levels answer different questions and neither substitutes for the other: the former describes the agent, the latter the containment appropriate to a specific manipulation. Our substantive concern is placement, not utility. Relocating the Risk Group listing from Appendix B into non-binding implementation resources removes the foundation on which the entire Section IV tiering rests, including the jurisdictional threshold, since wild-type Risk Group 1 work is outside the policy altogether. Section V-A compounds this by providing that absence from the listing does not imply Risk Group 1 classification, which makes classification an institutional judgment with no authoritative list behind it and no appeal. We recommend retaining the Risk Group listing as an appendix to the policy, with a published amendment process including notice and comment. We also suggest the idea of a federally maintained online database for Risk Groups, modeled on the current ABSA database. Deferring containment practice to the BMBL raises a parallel concern: a document written as non-regulatory guidance would carry mandatory obligations that change whenever CDC and NIH revise it.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary adoption depends on making the framework usable without an Assurance. Several of the policy's essential resources are currently tied to covered status: the Risk Group listing, NIH containment determinations for emerging and novel agents, and the published record of approved containment reductions. These should be openly available, since an unaffiliated institution cannot apply the framework without them, and a published determination benefits everyone who reads it. Three further mechanisms would help. First, a scaled model for smaller entities, including an express mechanism for shared or regional IBCs, since an independent institute or small company cannot assemble a five-member committee with two unaffiliated members. Second, access to the National Biosafety Data and Safety Analysis Center for non-covered entities, which is where voluntary participation produces the most public benefit, and which requires confidentiality protection on the model of patient safety work product before any institution's counsel will permit submission. Third, harmonization with ISO 35001 and ABSA credentialing so that voluntary adopters can demonstrate conformity through instruments they already use. We would caution against public posting as a condition of voluntary participation; it is the provision most likely to deter adoption. We would also note that the policy's extension to non-NIH-funded research at NIH-funded institutions is compliance by institutional association rather than voluntary compliance, and should not be counted as the latter.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Both templates are well constructed, and the redaction guidance in each is more developed than the policy text suggests; the policy itself should cross-reference it. Our concerns are specific.

Incident Reporting Template. The instruction to omit individual names and specific rooms is appropriate, but the combination of fields that must appear defeats de-identification in small groups: the named principal investigator, the full agent name and construct, the incident date, the position title of the person involved, training dates, and any injury, medical surveillance or treatment provided. In a five-person laboratory this is individually identifiable employee health information on a public webpage, engaging confidentiality obligations under the Americans with Disabilities Act, state occupational health and workers' compensation law, and HIPAA where occupational health sits within a covered entity. We recommend that the public version omit treatment and medical surveillance detail, reporting only whether an exposure resulted in illness, with the full detail supplied to NIH but not posted. Relatedly, the instruction that agents including Select Agents may not be redacted, combined with a named principal investigator and a containment-failure narrative, creates a biosecurity exposure that warrants a mechanism to seek NIH concurrence on withholding. The requirement that root cause analysis and corrective actions be posted publicly will shape what institutions are willing to write; we recommend considering a protection analogous to peer review or patient safety work product. The "failure to obtain or maintain IBC approval" checkbox routes administrative lapses through the same 24-hour channel and public posting as laboratory-acquired infections, which will discourage self-auditing; we recommend an annual summary for these instead, and in any case a field recording whether the institution identified the issue through its own monitoring. Finally, the prohibition on attachments limits the ability to provide supporting context, and the requirement that every field be completed in every final report should accommodate genuine non-applicability beyond a "not applicable" entry.
Meeting Minutes Template. The structure is workable and the allowance that delegated approvals may be attached as a list is helpful and should be carried into the policy text, which currently requires them to be reported in full. Three points to consider: 1) The background section states that posting applies to meetings on or after 1 June 2025, which appears to be carried over from the current transparency notice and should be restated by reference to the new policy's effective date. 2) The template recommends that quorum include at least one non-affiliated member, and leaves quorum itself to institutional policy; both the recommendation and a minimum quorum definition belong in the policy, since the template has no independent force and institutional variation on this point undermines the consistency the policy seeks. 3) The instruction that IBC member names may not be redacted, combined with the Assurance requirement for a continuously updated public roster, will make recruitment and retention of unaffiliated community members materially harder; we recommend publishing composition by role and expertise with named contacts limited to the Chair, the IBC Contact and the Biological Safety Officer.

6. Other feedback relevant to this resource: First and most important, the new policy needs a transition rule. The policy takes effect six months after publication and applies on that date to existing awards, ongoing intramural studies and all non-NIH-funded research at covered institutions, with no grandfathering. On the effective date an institution must simultaneously hold an approved Assurance, have converted a legacy registration portfolio to a three-year de novo cycle that does not currently exist, and have prospectively approved every newly in-scope activity. Anything not approved is being conducted without required approval, which the policy makes a reportable and publicly posted violation. We recommend a phased 24-month transition, with existing approvals remaining valid until scheduled conversion and an express provision that a pending conversion is not a compliance violation. Second, the Assurance itself: we need more guidance on the application, a review period, renewal continuity, the rule for multi-component institutions, and the treatment of externally administered IBCs including which entity bears the posting obligation. Will a template for Biosafety Assurance be provided and when?

Third, the Risk Group appendix and equivalence criteria for published containment determinations should be provided. Fourth, the new policy needs an express statement of the interface with the July 2026 USG Policy for Stopping High-Risk Life Sciences Research: which body screens first, whether IBC approval may issue before Institutional Review Entity classification, how referrals pass in both directions, and whether the deliberate transfer of drug resistance traits and the cloning of high-potency toxin genes, previously covered by Sections III-A and III-B-1, remain subject to heightened review under either framework. Fifth, the US Government should provide guidance on occupational health commensurate with the containment levels in use, since laboratory-acquired infection is the central reportable event while the policy imposes no affirmative occupational health requirement of its own. Sixth, we need more clarity on the limits of IBC purview for the risk assessment of clinical research when those risk are already covered by other mechanisms based on universal precautions. Finally, the other-agency provision in Section II should be rewritten to state that this policy's requirements apply in addition to, rather than in substitution for, those of other federal agencies; as drafted it reads as exempting Select Agent and FDA-regulated research, contradicting Section IV-2.

432. Brian H Davison

I am responding: On behalf of myself

Name: Brian H Davison

Name of Organization: ORNL

Type of Organization: Other

Type of Organization - Other: DOE national Laboratory

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biotechnology research and development in energy, industry, and environment

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The addition of biohazard review is broadly good. My institution already did this under contract rules, best practices and BMBL. this specifies biomedical biohazards. where do environmental or industrial biotechnology hazards come into view in this definition.
There is conflicting guidance with BMBL and APHIS on BSL1/2 practices etc. (they are close but not identical; there are too many differences to list).
Plant work is no longer covered. Recombinant work in plants should still be reviewed. there is not another community standard for transgenic plant research such as the BMBL.
This expands the remit but not always authority of the IBC.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I have Deep concern on the review of ALL proposals : especially as there are not clear statements on the level of review required. or how to enact this with appropriate triage. For example, can the PI certify that it is BSL1 and therefore “exempt” and thus no further review is required? Most every PROPOSAL have an independent review by the someone - such as the IBC or designee?
The “extra” new reviews and documentation will increase regulation and oversight and overhead with minimal improvement in biosafety. this is contrary to to OSTP report on "Science a new golden age" July 2026.

It is positive that IBC approval is required for lowering the containment for wild type or genetically modified RG2 biological agents. [This affirms our practice in using a graded approach that we have used for extremely small volumes and samples which are always under containment]

Limit NIH preapproval to defined high-risk or genuinely novel circumstances and allow local IBCs to rely on published NIH precedents.

Another positive is that “delegated review is now permitted for specific classes”

3. Continued utility of Risk Groups: RGs should remain the baseline for risk assessment. Then the BSL are used to contain and perform the work under a GRADED approach as outlined in the BMBL.

The extra review by NIH of “unknowns" will be onerous IF applied to environmental research. For example, the soil microbiome might contain pathogens but usually not and the direct risk is low. we have instituted checks to pause work if a pathogen is discovered during environmental isolation and cultivation.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): na

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: the policy is unclear on de minimus incident reporting. eg. Would the incident reporting be required for a needlestick of RG1 or BSL1 work where a nonspecific prophylactic antibiotic was administered as part of basic first aid and followed by monitoring? [non-agent specific treatment]. in the meeting template:
the public disclosure of biohazards and the naming of the PI publicly could comprise the worker identity safety outside of work. it may also compromise the awareness from adversaries under classified or export control regulations. There should be a mode for expurgated declassified release which allows the broad biosafety assessment with a declassified description and a redacted PI.

6. Other feedback relevant to this resource: there needs to be a phased implementations with changes based on this implementation pilot.
the cost of implementation should be considered. especially in the review of ALL proposals.

433. Kim Westervelt

I am responding: On behalf of myself

Name: Kim Westervelt

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comments-NIH-Draft-Biosafety-Policy-for-Research-Involving-Biohazards.docx

Docket ID: NOT-OD-26-112)
Title: NIH Draft Biosafety Policy for Research Involving Biohazards
Submitter/Category: Citizen Advocate

As a former NIH employee and now a concerned citizen advocate, I would like to make the following suggestions and comments on the proposed Biosafety Policy for Research Involving Biohazards.

We know that biosafety oversight works best when it directs attention and resources toward the activities that present meaningful risk. Transparency and accountability are important for everyone, but these actions must be done in a way that preserves researcher safety, encourages reporting, protects valuable research, and allows institutions to focus their oversight where it matters most.

Public Posting
If public posting remains part of the final policy, it should request anonymized, aggregated reporting, with identifiable information disclosed only when there is a legitimate need to know, such as during a public health investigation. The necessary recordkeeping needs to establish a clear baseline retention period and clarify how longer grant-specific requirements should apply when IBC registrations cover multiple projects or funding sources.

Reporting Thresholds
Establish reporting thresholds and clear up overlapping definitions between federal agencies so institutions aren't confused by duplicate or conflicting reporting rules.

Timeline
It would be helpful to provide a phased transition. Specifically, a minimum 24-month phased implementation period alongside pilot tests for new reporting and meeting-minute templates.

Additionally, to ensure these changes do not adversely impact the pursuit of research, it would be helpful to release a revised draft for public review before issuing a final policy.

Compliance Costs
Compliance costs will need to be addressed. Smaller colleges and non-R1 Research institutions with limited EHS/biosafety staff will potentially incur financial and operational constraints and will need guidance and resources.

Please consider how all these new requirements could affect scientists and their pursuit of medical progress, their institutions, and the conduct of biomedical research in the US.

Thank you for the opportunity to comment.
Kim Westervelt

434. Engineering Biology Research Consortium

I am responding: On behalf of an organization

Name: Rodney Eric Williams

Name of Organization: Engineering Biology Research Consortium

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Synthetic and Engineering Biology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: EBRC supports expanding NIH's biosafety policy beyond research involving recombinant or synthetic nucleic acid molecules to encompass a broader range of biological research that may involve biohazards. However, a broader scope need not create broader administrative requirements or ambiguous oversight frameworks. Clear definitions and decision criteria will be essential to ensure institutions can consistently determine which research activities fall within scope and what level of oversight is warranted. Without clear boundaries and predictable criteria, the expanded scope could create uncertainty about which activities require oversight. This uncertainty may discourage institutions from pursuing otherwise appropriate research and have a chilling effect on research and innovation without corresponding improvements in biosafety.

The expansion of scope also raises questions about how this policy will interact with existing federal biosafety, biosecurity, and research oversight requirements. Depending on the research activity, biological agent, and funding source, a project may be subject to oversight and review from multiple other federal funding and oversight agencies (e.g., CDC, DHS, USDA), and the U.S. Government Policy for Stopping High-Risk Life Sciences Research. Together, these policies could significantly expand review, approval, and reporting obligations for engineering biology research, including synthetic biology, engineered biological systems, and pathogen-related research. Without clear coordination, the expanded policy could create duplicative reviews, conflicting requirements, or uncertainty about which agency's processes should be followed and in what order.

NIH should therefore:

-Provide clear definitions, decision criteria, and practical examples for determining which research activities fall within scope, particularly those involving genetically modified organisms, synthetic biological systems, and changes resulting from serial passaging or reassortment.

-Ensure that oversight requirements reflect meaningful biosafety risks rather than the presence of a

particular biological material or modification alone, and exempt or streamline requirements for well-characterized, low-risk research where additional oversight offers little-to-no safety benefit.

-Clarify how the policy applies to emerging or engineered biological systems that do not fit established definitions or classifications, including how institutions should determine whether the research falls within scope when there is no clear precedent.

-Clarify which activities at NIH-funded institutions are covered when the research itself is not NIH-funded, including how institutions should identify covered activities without creating unnecessary compliance obligations for unrelated research.

-Clarify how the policy interacts with biosafety, biosecurity, and research oversight requirements imposed by other federal agencies, including how overlapping or potentially conflicting requirements will be reconciled when research is subject to multiple federal policies or funding conditions.

-Specifically clarify the relationship between this policy and the U.S. Government Policy for Stopping High-Risk Life Sciences Research, including how institutions should determine which requirements apply when research falls within the scope of both policies and how to navigate their respective review, approval, and compliance processes.

A broader policy can strengthen biosafety, but its reach must be justified, clearly defined, and proportionate to risk. NIH must ensure that expanded coverage delivers meaningful safety benefits without unnecessarily extending institutional compliance obligations.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed framework establishes distinct roles for NIH, institutions, IBCs, and investigators, with different levels of review based on the nature and risk of the research. Its effectiveness will depend on whether these responsibilities are clearly defined, oversight is proportionate to risk, and accountability measures promote biosafety without creating unnecessary administrative burden. Delegated review is an important part of this balance, allowing IBCs to focus their time and expertise on higher-risk or more uncertain research rather than routine activities that can be assessed against established criteria. Ultimately, the framework should direct oversight resources where they can meaningfully reduce risk, rather than add procedural requirements that do not improve biosafety.

NIH should therefore:

-Clearly define the circumstances that warrant NIH review and explain what specific or additional safety benefit NIH-level review is intended to provide beyond institutional assessment.

-Establish clear criteria that support predictable escalation decisions without requiring NIH review solely because a system is novel or its risk profile is not fully characterized.

-Preserve flexibility for institutions to delegate review of routine, well-characterized, low-risk activities beyond the specific categories enumerated in the policy, using predefined criteria and clear escalation pathways when risks or uncertainties warrant full IBC review.

-Establish predictable timelines for federal review–including target timelines for initial review, any requests for additional information, and final decisions–along with a process for communicating delays and resolving stalled reviews.

-Ensure that documentation, public reporting, and incident-reporting requirements are proportionate to risk, clearly defined, and consistently applied, with appropriate protections for confidential, proprietary, and security-sensitive information.

-Coordinate NIH requirements with existing institutional biosafety, research compliance, and incident-reporting processes to minimize duplicative administrative work for institutions and investigators.

-Ensure that NIH review and approval requirements account for existing oversight by other federal agencies, avoiding duplicative review, inconsistent requirements, and unnecessary delays where research activities or risks are already subject to other federal oversight.
- For example, clarify how NIH review under this draft policy for changes involving the risk group or safety level classification of biohazards should interact with ITPRB review under the U.S. Government Policy for Stopping High-Risk Life Sciences Research.

-Evaluate the policy's implementation by collecting data on IBC workload, review timelines, institutional resources, reporting burden, and effects on research timelines and activity, and use those findings to revise requirements and oversight levels that impose burdens disproportionate to their biosafety benefits.

A successful, tiered framework must strengthen accountability while directing oversight resources where they can have the greatest impact. Clear responsibilities, proportionate reporting requirements, timely review, and flexibility for delegated review will help institutions maintain effective biosafety programs without unnecessarily delaying responsible research.

3. Continued utility of Risk Groups: The draft appropriately recognizes that Risk Group and Biosafety Level classifications are related but not equivalent and that containment decisions must account for the specific research being conducted. However, additional guidance is needed to clarify how the different factors identified in this policy should be weighed when assessing genetically modified and synthetic biological systems – particularly when modifications alter the characteristics of a parent agent or when established classifications provide limited information about a novel system.

NIH should therefore:

-Provide practical criteria and examples for determining how RG classifications, genetic modifications, and experimental manipulations should inform containment decisions. In particular, clarify how investigators and IBCs should weigh factors such as changes in pathogenicity, transmissibility, host range, and toxicity when these factors do not point to a consistent risk determination.

-Establish clear expectations for the supporting evidence and documentation investigators and IBCs must provide to justify risk assessments and resulting containment decisions to ensure efficient, transparent,

and consistent review processes.

-Clarify how experiment-specific approvals to lower containment differ from revisions to an agent's RG classification. NIH should provide guidance on how to document and communicate these distinct determinations so that approval to handle a specific attenuated strain at a lower BSL is not misinterpreted as changing the agent's RG classification.

-Clarify how the policy's minimum containment requirements interact with provisions for lower-containment determinations. Section V-E establishes a minimum of BSL-2 for research involving GDMOs, while Sections III-B and IV-1 provide for NIH review of initial requests to lower containment below BSL-2 for GDMOs and to lower containment for RG3/RG4 agents. NIH should clarify the criteria for evaluating these requests, including how evidence of attenuation or loss of function and other risk-reducing modifications should inform containment decisions, and explain how these provisions interact with the policy's stated minimum containment requirements.

-Provide additional guidance for risk assessment of synthetic and engineered biological systems that combine sequences from multiple sources or do not fit readily within established RG classifications. Section V-C identifies source RG classifications, the percentage of the genome contributed by each source, encoded functions, and potential synergistic effects as relevant considerations. NIH should clarify:
-How these factors should be weighed when they suggest different levels of risk;
-How the assumption that sequences will encode functions as they did in their original host should be applied alongside consideration of their effects in a new biological context, including potentially unexpected or synergistic effects; and
-What evidence and documentation are needed to characterize and assess uncertainty in the resulting system's risk profile.

Clearer criteria for weighing risk factors, interpreting minimum containment requirements, and determining when federal review is necessary would help institutions apply the policy consistently while preserving experiment-specific scientific judgment. NIH should focus additional review on cases where it provides meaningful value in addressing risk or uncertainty, rather than relying on classifications alone to determine the appropriate level of containment or oversight.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Strengthening biosafety requires a shared commitment across the research ecosystem. The draft policy has the potential to advance this goal, but its effectiveness will depend in part on whether institutions and researchers are encouraged to report concerns, learn from safety events, and address deficiencies in good-faith. EBRC encourages NIH to pair clear expectations and appropriate accountability with safeguards that promote transparency, trust, and continuous improvement.

NIH should consider approaches that:

-Prioritize corrective action, technical assistance, and learning over punitive measures for accidents or inadvertent noncompliance.

Establish clear criteria for escalating responses to intentional or reckless violations, repeated noncompliance, or failure to take timely and adequate corrective action.

-Clarify institutional and Biological Safety Officer (BSO) responsibilities to promote accountability without unfairly assigning individual blame for broader institutional failures.

-Ensure incident reporting and public-posting requirements promote transparency and shared learning while protecting personal, proprietary, and security-sensitive information.

-Provide clear, consistent redaction criteria for public reporting requirements and safeguards against unnecessarily exposing sensitive research, personnel, or institutional reputations in ways that could discourage good-faith incident reporting.

-Recognize the proposed National Biosafety Data and Safety Analysis Center (NBDSAC) as an opportunity to promote shared learning from incidents, near-misses, and other safety events. Good-faith reporting should support prevention and continuous improvement, not become a basis for punitive identification of institutions or individuals.

-Contribute to coordination across federal agencies and oversight frameworks, including clearer guidance on the relationship between biosafety and biosecurity requirements, to reduce fragmented or duplicative obligations and support consistent biosafety practices.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft IBC meeting-minutes and incident-reporting templates will shape how institutions document committee decisions and report biosafety incidents. The templates should provide clear instructions and allow institutions to meet these requirements without unnecessary or duplicative documentation.

NIH should therefore:

-Revise the draft IBC meeting-minutes and incident-reporting templates in response to stakeholder feedback.

-Establish clear mechanisms and processes for initial and final reports, the submission of supplemental information, and consistent redaction of personal, proprietary, and security-sensitive information before public posting.

-Clarify the safeguards governing the use of reported information about principal investigators (PIs), ensuring that it is used to promote biosafety and address substantiated concerns rather than as a basis for unwarranted punitive action.

-Clearly define the minimum documentation needed to record IBC deliberations and decisions.

-Allow cross-referencing of existing institutional records where appropriate to avoid duplicative documentation.

-Clarify the intended start date for the meeting-minutes public-posting requirement, including its relationship to the policy's effective date, and provide consistent criteria for redacting personal, proprietary, and security-sensitive information.

6. Other feedback relevant to this resource: Effective implementation will require clear guidance on the policy's requirements and how institutions are expected to apply them in practice. The draft policy introduces expanded biosafety oversight and detailed documentation, public posting, and incident-reporting requirements. For this policy to be effective and beneficial, NIH must provide practical support to help institutions interpret these requirements consistently, assess and plan for staffing and expertise needed for implementation, and avoid unnecessary administrative burden.

NIH should therefore:

-Solicit stakeholder feedback on draft implementation materials, including guidance, decision trees, and reporting and documentation templates. NIH should publish draft materials promptly after finalizing the policy, allow at least 30 days for feedback, and summarize how substantive comments were addressed in the final materials.

-Develop practical decision trees and examples showing which research activities are covered, which oversight tier applies, when NIH approval is required, when delegated review is appropriate, and how genetically modified and synthetic biological systems should be evaluated.
-Examples should address both straightforward cases and situations in which the scope, risk classification, or appropriate containment level is uncertain.

-Provide a crosswalk from the current NIH Guidelines to the new policy, identifying requirements that are retained, modified, eliminated, or newly introduced, and explaining how existing institutional processes should be adapted.
-The crosswalk should specifically identify new institutional obligations, including public posting, record retention, and incident reporting.

-Maintain the draft policy's six-month transition period, with final implementation guidance, decision trees, crosswalks, and templates available at least 90 days before the effective date. If NIH cannot meet that timeline, it should extend the effective date as needed to preserve a meaningful period for institutional preparation.

-Establish a six-month grace period after the effective date for good-faith administrative deficiencies arising from new documentation, public-posting, and procedural requirements. During this period, NIH should prioritize technical assistance and corrective action over enforcement, while maintaining substantive biosafety, prior-approval, and incident-reporting requirements.

-Establish clear timelines for NIH review, including target timeframes for acknowledging requests, identifying missing information, and issuing decisions.
For example, NIH could aim to acknowledge submissions within 10 business days and provide an initial determination or a timeline for resolution within 60 calendar days of receiving a complete submission.
-NIH should explain how delays will be communicated and provide points of contact for questions and

unresolved cases.

-Request that OSTP establish an interagency working group, or use an existing interagency forum, with relevant federal agencies to develop aligned implementation guidance and clarify how this policy interacts with other biosafety, biosecurity, and incident-reporting requirements.
-The group should identify conflicting or duplicative obligations, coordinate relevant definitions and reporting expectations, and communicate agreed-upon approaches to institutions.

-Include a cross-agency policy crosswalk in the implementation materials to help institutions determine which requirements apply based on the research activity, biological agent, and relevant funding or oversight arrangements.

-Review implementation after the first year and publish a summary of feedback and operational data, including review timelines, institutional workload, recurring interpretation questions, and challenges with documentation and reporting.
-NIH should use these findings to clarify guidance and adjust implementation where requirements create burdens disproportionate to their biosafety benefits.

Successful implementation will depend on more than publication of the final policy. Timely guidance, a meaningful opportunity for stakeholder feedback, predictable review timelines, and a proportionate transition to new administrative requirements will help institutions apply the policy consistently while maintaining effective biosafety oversight.

Uploaded File: EBRC-Response_NIH-Draft-Biosafety-Policy-RFI.pdf

Description: Full official EBRC response, including an organizational overview and an introductory position statement, on organizational letterhead

EBRC Engineering Biology Research Consortium

Response to NIH Request for Information on
Draft NIH Biosafety Policy for Research Involving Biohazards

Notice Number: NOT-OD-26-1120

19 October 2026

The Engineering Biology Research Consortium (EBRC) is a nonprofit, public-private partnership that brings together scientists, engineers, and industry leaders to advance the field of engineering biology to address national and global needs. EBRC's members include experts from over 100 universities and research institutes, alongside leaders from more than 30 companies, philanthropies, and other organizations. Working closely with partners across the engineering biology ecosystem, EBRC focuses on four key areas: Research Roadmapping, Policy & International Engagement, Education, and Security.

EBRC welcomes the opportunity to respond to the National Institutes of Health (NIH) Request for Information on its Draft NIH Biosafety Policy for Research Involving Biohazards. EBRC supports modernizing biosafety oversight to address the breadth of contemporary biomedical research, including genetically modified organisms, synthetic biological systems, and emerging engineering biology technologies. Given the diversity of biological systems, modifications, and research applications, an effective policy should establish clear definitions, risk-proportionate oversight, transparent institutional responsibilities, and practical implementation guidance while avoiding unnecessary administrative burden, duplicative review, and delays that do not meaningfully improve biosafety. EBRC encourages NIH to implement a clear, flexible, and risk-based framework that strengthens biosafety practices, promotes accountability and evidence-based learning, and supports rigorous, innovative, and responsible research.

1. Appropriateness of Scope of New Policy

EBRC supports expanding NIH's biosafety policy beyond research involving recombinant or synthetic nucleic acid molecules to encompass a broader range of biological research that may involve biohazards. However, a broader scope need not create broader administrative requirements or ambiguous oversight frameworks. Clear definitions and decision criteria will be essential to ensure institutions can consistently determine which research activities fall within scope and what level of oversight is warranted. Without clear boundaries and predictable criteria, the expanded scope could create uncertainty about which activities require oversight. This uncertainty may discourage institutions from pursuing otherwise appropriate research and have a chilling effect on research and innovation without corresponding improvements in biosafety.

The expansion of scope also raises questions about how this policy will interact with existing federal biosafety, biosecurity, and research oversight requirements. Depending on the research activity, biological agent, and funding source, a project may be subject to oversight and review from multiple other federal funding and oversight agencies (e.g., CDC, DHS, USDA), and the U.S.

Government Policy for Stopping High-Risk Life Sciences Research. Together, these policies could significantly expand review, approval, and reporting obligations for engineering biology research, including synthetic biology, engineered biological systems, and pathogen-related research. Without clear coordination, the expanded policy could create duplicative reviews, conflicting requirements, or uncertainty about which agency's processes should be followed and in what order.

NIH should therefore:

- Provide clear definitions, decision criteria, and practical examples for determining which research activities fall within scope, particularly those involving genetically modified organisms, synthetic biological systems, and changes resulting from serial passaging or reassortment.
- Ensure that oversight requirements reflect meaningful biosafety risks rather than the presence of a particular biological material or modification alone, and exempt or streamline requirements for well-characterized, low-risk research where additional oversight offers little-to-no safety benefit.
- Clarify how the policy applies to emerging or engineered biological systems that do not fit established definitions or classifications, including how institutions should determine whether the research falls within scope when there is no clear precedent.
- Clarify which activities at NIH-funded institutions are covered when the research itself is not NIH-funded, including how institutions should identify covered activities without creating unnecessary compliance obligations for unrelated research.
- Clarify how the policy interacts with biosafety, biosecurity, and research oversight requirements imposed by other federal agencies, including how overlapping or potentially conflicting requirements will be reconciled when research is subject to multiple federal policies or funding conditions.
- Specifically clarify the relationship between this policy and the U.S. Government Policy for Stopping High-Risk Life Sciences Research, including how institutions should determine which requirements apply when research falls within the scope of both policies and how to navigate their respective review, approval, and compliance processes.

A broader policy can strengthen biosafety, but its reach must be justified, clearly defined, and proportionate to risk. NIH must ensure that expanded coverage delivers meaningful safety benefits without unnecessarily extending institutional compliance obligations.

2. Appropriateness of Tiered Oversight & Calibration to Risks

The proposed framework establishes distinct roles for NIH, institutions, IBCs, and investigators, with different levels of review based on the nature and risk of the research. Its effectiveness will depend on whether these responsibilities are clearly defined, oversight is proportionate to risk, and accountability measures promote biosafety without creating unnecessary administrative

burden. Delegated review is an important part of this balance, allowing IBCs to focus their time and expertise on higher-risk or more uncertain research rather than routine activities that can be assessed against established criteria. Ultimately, the framework should direct oversight resources where they can meaningfully reduce risk, rather than add procedural requirements that do not improve biosafety.

NIH should therefore:

- Clearly define the circumstances that warrant NIH review and explain what specific or additional safety benefit NIH-level review is intended to provide beyond institutional assessment.
- Establish clear criteria that support predictable escalation decisions without requiring NIH review solely because a system is novel or its risk profile is not fully characterized.
- Preserve flexibility for institutions to delegate review of routine, well-characterized, low-risk activities beyond the specific categories enumerated in the policy, using predefined criteria and clear escalation pathways when risks or uncertainties warrant full IBC review.
- Establish predictable timelines for federal review–including target timelines for initial review, any requests for additional information, and final decisions–along with a process for communicating delays and resolving stalled reviews.
- Ensure that documentation, public reporting, and incident-reporting requirements are proportionate to risk, clearly defined, and consistently applied, with appropriate protections for confidential, proprietary, and security-sensitive information.
- Coordinate NIH requirements with existing institutional biosafety, research compliance, and incident-reporting processes to minimize duplicative administrative work for institutions and investigators.
- Ensure that NIH review and approval requirements account for existing oversight by other federal agencies, avoiding duplicative review, inconsistent requirements, and unnecessary delays where research activities or risks are already subject to other federal oversight.
    - For example, clarify how NIH review under this draft policy for changes involving the risk group or safety level classification of biohazards should interact with ITPRB review under the U.S. Government Policy for Stopping High-Risk Life Sciences Research.
- Evaluate the policy's implementation by collecting data on IBC workload, review timelines, institutional resources, reporting burden, and effects on research timelines and activity, and use those findings to revise requirements and oversight levels that impose burdens disproportionate to their biosafety benefits.

A successful, tiered framework must strengthen accountability while directing oversight resources where they can have the greatest impact. Clear responsibilities, proportionate reporting requirements, timely review, and flexibility for delegated review will help institutions maintain effective biosafety programs without unnecessarily delaying responsible research.

3. Risk Groups, Biosafety Levels, and Risk Assessment

The draft appropriately recognizes that Risk Group and Biosafety Level classifications are related but not equivalent and that containment decisions must account for the specific research being conducted. However, additional guidance is needed to clarify how the different factors identified in this policy should be weighed when assessing genetically modified and synthetic biological systems – particularly when modifications alter the characteristics of a parent agent or when established classifications provide limited information about a novel system.

NIH should therefore:

- Provide practical criteria and examples for determining how RG classifications, genetic modifications, and experimental manipulations should inform containment decisions. In particular, clarify how investigators and IBCs should weigh factors such as changes in pathogenicity, transmissibility, host range, and toxicity when these factors do not point to a consistent risk determination.
- Establish clear expectations for the supporting evidence and documentation investigators and IBCs must provide to justify risk assessments and resulting containment decisions to ensure efficient, transparent, and consistent review processes.
- Clarify how experiment-specific approvals to lower containment differ from revisions to an agent's RG classification. NIH should provide guidance on how to document and communicate these distinct determinations so that approval to handle a specific attenuated strain at a lower BSL is not misinterpreted as changing the agent's RG classification.
- Clarify how the policy's minimum containment requirements interact with provisions for lower-containment determinations. Section V-E establishes a minimum of BSL-2 for research involving GDMOs, while Sections III-B and IV-1 provide for NIH review of initial requests to lower containment below BSL-2 for GDMOs and to lower containment for RG3/RG4 agents. NIH should clarify the criteria for evaluating these requests, including how evidence of attenuation or loss of function and other risk-reducing modifications should inform containment decisions, and explain how these provisions interact with the policy's stated minimum containment requirements.
- Provide additional guidance for risk assessment of synthetic and engineered biological systems that combine sequences from multiple sources or do not fit readily within established RG classifications. Section V-C identifies source RG classifications, the percentage of the genome contributed by each source, encoded functions, and potential synergistic effects as relevant considerations. NIH should clarify:
    - How these factors should be weighed when they suggest different levels of risk;
    - How the assumption that sequences will encode functions as they did in their original host should be applied alongside consideration of their effects in a new biological context, including potentially unexpected or synergistic effects; and

- What evidence and documentation are needed to characterize and assess uncertainty in the resulting system's risk profile.

Clearer criteria for weighing risk factors, interpreting minimum containment requirements, and determining when federal review is necessary would help institutions apply the policy consistently while preserving experiment-specific scientific judgment. NIH should focus additional review on cases where it provides meaningful value in addressing risk or uncertainty, rather than relying on classifications alone to determine the appropriate level of containment or oversight.

4. Voluntary Compliance and Strengthening the Broader Biosafety Ecosystem

Strengthening biosafety requires a shared commitment across the research ecosystem. The draft policy has the potential to advance this goal, but its effectiveness will depend in part on whether institutions and researchers are encouraged to report concerns, learn from safety events, and address deficiencies in good-faith. EBRC encourages NIH to pair clear expectations and appropriate accountability with safeguards that promote transparency, trust, and continuous improvement.

NIH should consider approaches that:

- Prioritize corrective action, technical assistance, and learning over punitive measures for accidents or inadvertent noncompliance.
- Establish clear criteria for escalating responses to intentional or reckless violations, repeated noncompliance, or failure to take timely and adequate corrective action.
- Clarify institutional and Biological Safety Officer (BSO) responsibilities to promote accountability without unfairly assigning individual blame for broader institutional failures.
- Ensure incident reporting and public-posting requirements promote transparency and shared learning while protecting personal, proprietary, and security-sensitive information.
- Provide clear, consistent redaction criteria for public reporting requirements and safeguards against unnecessarily exposing sensitive research, personnel, or institutional reputations in ways that could discourage good-faith incident reporting.
- Recognize the proposed National Biosafety Data and Safety Analysis Center (NBDSAC) as an opportunity to promote shared learning from incidents, near-misses, and other safety events. Good-faith reporting should support prevention and continuous improvement, not become a basis for punitive identification of institutions or individuals.
- Contribute to coordination across federal agencies and oversight frameworks, including clearer guidance on the relationship between biosafety and biosecurity requirements, to reduce fragmented or duplicative obligations and support consistent biosafety practices.

5. Draft Incident Reporting and Draft Meeting Minutes Templates

The draft IBC meeting-minutes and incident-reporting templates will shape how institutions document committee decisions and report biosafety incidents. The templates should provide clear instructions and allow institutions to meet these requirements without unnecessary or duplicative documentation.

NIH should therefore:

- Revise the draft IBC meeting-minutes and incident-reporting templates in response to stakeholder feedback.
- Establish clear mechanisms and processes for initial and final reports, the submission of supplemental information, and consistent redaction of personal, proprietary, and security-sensitive information before public posting.
- Clarify the safeguards governing the use of reported information about principal investigators (PIs), ensuring that it is used to promote biosafety and address substantiated concerns rather than as a basis for unwarranted punitive action.
- Clearly define the minimum documentation needed to record IBC deliberations and decisions.
- Allow cross-referencing of existing institutional records where appropriate to avoid duplicative documentation.
- Clarify the intended start date for the meeting-minutes public-posting requirement, including its relationship to the policy's effective date, and provide consistent criteria for redacting personal, proprietary, and security-sensitive information.

6. Implementation, Guidance, and Institutional Readiness

Effective implementation will require clear guidance on the policy's requirements and how institutions are expected to apply them in practice. The draft policy introduces expanded biosafety oversight and detailed documentation, public posting, and incident-reporting requirements. For this policy to be effective and beneficial, NIH must provide practical support to help institutions interpret these requirements consistently, assess and plan for staffing and expertise needed for implementation, and avoid unnecessary administrative burden.

NIH should therefore:

- Solicit stakeholder feedback on draft implementation materials, including guidance, decision trees, and reporting and documentation templates. NIH should publish draft materials promptly after finalizing the policy, allow at least 30 days for feedback, and summarize how substantive comments were addressed in the final materials.
- Develop practical decision trees and examples showing which research activities are covered, which oversight tier applies, when NIH approval is required, when delegated review is appropriate, and how genetically modified and synthetic biological systems should be evaluated.

    - Examples should address both straightforward cases and situations in which the scope, risk classification, or appropriate containment level is uncertain.
- Provide a crosswalk from the current NIH Guidelines to the new policy, identifying requirements that are retained, modified, eliminated, or newly introduced, and explaining how existing institutional processes should be adapted.
    - The crosswalk should specifically identify new institutional obligations, including public posting, record retention, and incident reporting.
- Maintain the draft policy's six-month transition period, with final implementation guidance, decision trees, crosswalks, and templates available at least 90 days before the effective date. If NIH cannot meet that timeline, it should extend the effective date as needed to preserve a meaningful period for institutional preparation.
- Establish a six-month grace period after the effective date for good-faith administrative deficiencies arising from new documentation, public-posting, and procedural requirements. During this period, NIH should prioritize technical assistance and corrective action over enforcement, while maintaining substantive biosafety, prior-approval, and incident-reporting requirements.
- Establish clear timelines for NIH review, including target timeframes for acknowledging requests, identifying missing information, and issuing decisions.
    - For example, NIH could aim to acknowledge submissions within 10 business days and provide an initial determination or a timeline for resolution within 60 calendar days of receiving a complete submission.
    - NIH should explain how delays will be communicated and provide points of contact for questions and unresolved cases.
- Request that OSTP establish an interagency working group, or use an existing interagency forum, with relevant federal agencies to develop aligned implementation guidance and clarify how this policy interacts with other biosafety, biosecurity, and incident-reporting requirements.
    - The group should identify conflicting or duplicative obligations, coordinate relevant definitions and reporting expectations, and communicate agreed-upon approaches to institutions.
- Include a cross-agency policy crosswalk in the implementation materials to help institutions determine which requirements apply based on the research activity, biological agent, and relevant funding or oversight arrangements.
- Review implementation after the first year and publish a summary of feedback and operational data, including review timelines, institutional workload, recurring interpretation questions, and challenges with documentation and reporting.
    - NIH should use these findings to clarify guidance and adjust implementation where requirements create burdens disproportionate to their biosafety benefits.

Successful implementation will depend on more than publication of the final policy. Timely guidance, a meaningful opportunity for stakeholder feedback, predictable review timelines, and a proportionate transition to new administrative requirements will help institutions apply the policy consistently while maintaining effective biosafety oversight.

435. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: What is the rational behind registering and reviewing a risk assessment for low level transgenic organisms, such as C. elegans, drosophila, murine rodents housed at ABSL-1, that can not cause human or animal disease. These all fall out of the scope of the newly proposed policy. The amount of effort to capture these vast quantities of organism and asses a risk that doesn't exist, over and over again, is a huge drain on biosafety professionals and takes away from vital support of researchers without any real benefit to safety or security. IF all organism do need to be registered at an institution receiving NIH funding, such low risk organisms as mentioned above should be captured under a blanket registration for the university.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: "Research with primary cells that may be contaminated by adventitious agents." Does this include all human cells? Under OSHA, all human cells are already considered potentially infected unless tested for a short list of BBP. But, in reality, the risk from one human cell, whether established or primary, does NOT CHANGE the risk assessment!!! Why would all human primary cells have to be registered? Some modified primary cells are in existence for a very short time (as they are unwanted outcomes and instantly destroyed) and registering them doesn't make sense for material that no longer exists. All other established human cells already have mitigation measure in place to handle them safely.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please consider removing the need to report to NIH for failure to have IBC protocols for previously exempt experiments. It's hard enough to capture work that has risk and has to be captured for review. The need to register all transgenic mice and drosophila or all modified human cell lines does not change risk and does not increase safety. This burden to capture the material requested in this proposed policy will actually harm our researches and not provide any useful outcomes to create safer work environments! This policy

seems to be more about big brother watching rather than updating biosafety application to our researchers and lab spaces. Biosafety professionals will have less time to perform risk assessments on procedures and labs handling material. The requirements of report exposures and spills will reduce researchers reaching out to biosafety professionals for help.

6. Other feedback relevant to this resource: The cost and time of implementing the proposed guidelines with be far beyond what most institutions have available, including the staff needed to get a new program together and delivered. It takes about 2 years to generate, test, and implement a new registration platform, so the 6month time-line would not be anywhere enough.

436. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Biosafety Professionals Are Assigned Responsibilities Without Corresponding Authority

Observation
The proposed policy substantially expands the role of biosafety professionals in inspections, incident response, reporting, consultation, and oversight activities.
However, the draft does not appear to establish corresponding authority.

Real-World Implementation Impact
In a real institution, biosafety professionals are often expected to:
• Investigate incidents;
• Identify hazards;
• Recommend corrective actions;
• Monitor compliance;
• Support IBC oversight; and
• Advise institutional leadership.

Yet the policy does not clearly specify whether they have authority to:
• Access required records;
• Enter laboratories when necessary;
• Require corrective actions;
• Escalate unresolved concerns;
• Suspend unsafe activities; or
• Elevate significant concerns beyond departmental management.
The result is an accountability mismatch.
An individual may be held responsible for identifying and addressing risks without being given sufficient authority to ensure those risks are addressed.

Why This Matters
Successful safety programs depend on clear accountability structures. Authority and responsibility should be aligned.
If biosafety professionals are expected to serve as key components of a risk-based oversight system, they should possess the authority necessary to carry out those responsibilities effectively.

Recommendation
NIH should establish clear expectations regarding:
1. Minimum authority.
2. Escalation pathways.
3. Access rights.
4. Corrective-action authority.
5. Communication with institutional leadership.
Clarifying authority would strengthen implementation and improve accountability.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

437. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Authorized Organizational Representative Role Requires Greater Clarity

Observation
The proposed Authorized Organizational Representative (AOR) role appears to assume responsibilities that are often distributed among multiple individuals within existing research governance structures. The function and authority of the role are not fully defined.

Real-World Implementation Impact
In practice, institutions may assign the role to:
• Biosafety professionals;
• Institutional Officials;
• Research compliance leaders;
• Signing Officials;
• Vice Presidents for Research;
• Research Integrity Officers; or
• Other senior administrators.
As written, different institutions may select entirely different governance models.

This creates uncertainty regarding:
• Accountability;
• Authority;
• Reporting relationships;
• Institutional commitments; and
• Decision-making responsibilities.
Investigators, IBCs, and biosafety staff may also be unclear regarding when concerns should be elevated to the AOR.

Why This Matters
A role intended to improve accountability may instead create inconsistency if institutions interpret the position differently.
The Biosafety Assurance appears designed to represent institutional commitments. Such commitments are most effective when responsibility and authority are clearly defined.

Recommendation
NIH should provide guidance regarding:
1. Purpose of the position.
2. Required authority.
3. Reporting relationships.
4. Relationship to the IBC and biosafety program.
5. Example governance structures for different institution types.
Clear governance expectations would improve consistency across the research enterprise.

438. Texas Biomedical Research Institute

I am responding: On behalf of an organization

Name: Hsiang-Ming Wang

Name of Organization: Texas Biomedical Research Institute

Type of Organization: Non-Profit Research Organization

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed policy defines biological agents as pathogens that cause disease in humans only, excluding animals or plants. This is a narrow definition that deviates from a "One Health" approach. The Federal Select Agent Program (FSAP) provides an excellent model for cross-agency collaboration on biological hazard oversight. This proposed policy expands the scope of human pathogens but may create confusion by excluding animal and plant-specific pathogens that were included under the prior NIH Guidelines. At the same time, there should be either a coordinated sister policy that covers animal- and plant- specific pathogens or, ideally, a single comprehensive policy that covers all biological hazards affecting the health of humans, animals, and plants.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed tiered oversight linked to calibration of risk is appropriate. However, the proposed timeline for renewals may generate confusion and potential non-compliance as Institutional Biosafety Committee (IBC) protocols must be renewed every 3 years, whereas Biosafety Assurance is required every 4 years, and many NIH grants renew on a 5-year cycle. Synchronization of these timelines would streamline oversight and reduce confusion. NIH should, at a minimum, provide automated reminders for the renewal of Biosafety Assurance for registered entities.

3. Continued utility of Risk Groups: The continued use of Risk Groups is appropriate. However, what is missing is a process to ensure timely updates and publishing of "approved determinations of appropriate lower containment for research involving wild type or genetically modified RG3 or RG4 biological agents". Specifically, Appendix D of the current NIH Guidelines have not been kept up to date, resulting in inconsistencies and lack of transparency in the evaluation process and requirements for lowering containment. One solution would be to create an active database that is updated at least quarterly and contains pertinent information on specific approved conditions where lower Biosafety Level is granted for the indicated agents. This approach will reduce the administrative burden on both NIH and the regulated entities while maximizing the sharing of scientific knowledge.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Clear guidance of required information to be submitted must protect the individual and institution willing to share this information. To maximize the effectiveness, voluntary reports, including near-miss incidents, should be protected from Freedom of Information Act (FOIA) inquiries and used for shared learning instead of fault-finding.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The types of incidents that must be reported to NIH need to be better defined and described along with concrete examples. A requirement to "post all incident reports on a public facing webpage" combined with lack of clarity regarding how incidents are defined could lead to misinterpretation and extra administrative burden with no benefit in risk reduction. Moreover, to avoid double reporting, the Federally Funded Research and Development Center (FFRDC) must coordinate and synchronize data with other reporting requirements of the FSAP and the Occupational Safety and Health Administration (OSHA), including, but not limited to, a shared platform for incident reporting and/or use of a unified reporting template. The lack of inter-agency coordination results in redundant incident reporting requirements that significantly increase the administrative burden at the regulated entities.

6. Other feedback relevant to this resource: Implementation resources in the following areas should be provided
- Concrete example of each review category
- Requests for reducing biosafety level
- Incident reporting requirements and information needed for these reports
- Template/guidelines for all materials that need to be posted publicly

This is not an exhaustive list.

439. Sabai Global

I am responding: On behalf of an organization

Name: Garry Coulson

Name of Organization: Sabai Global

Type of Organization: Institutional Research Oversight Committees e.g. IRB

Role: Other

Role - Other: Senior Director, Institutional Partnerships & Biosafety Advisor

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Clinical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Sabai supports the overarching aim of the draft Policy to modernize biosafety oversight so that it is transparent, adaptive, and accountable. We commend the National Institutes of Health (NIH) for several changes that, in our view, strengthen biosafety practice. First, extending the Policy beyond recombinant and synthetic nucleic acid molecules to wild type biological agents, toxins, prions, and self-aggregating proteins, and applying it to non-NIH-funded research at institutions that receive any NIH funding closes gaps in the current NIH Guidelines. Second, the risk-tiered structure of Section IV, which provides for NIH and Institutional Biosafety Committee (IBC) review of research with the greatest uncertainty, IBC review of most other research, and delegated review of lower-risk research, is well calibrated and should reduce burden where risk is low. Third, the written Biosafety Assurance approved by NIH and the standardized meeting minutes and incident reporting templates will promote accountability and consistency across institutions. Fourth, the Section V risk assessment framework, which starts from the parent agent, accounts for genetic modification and manipulations, and is harmonized with the Biosafety in Microbiological and Biomedical Laboratories (BMBL), gives IBCs a clear and defensible method for assessing risk.

The comments below address the scope of the draft Policy, with particular attention to the proposed oversight of clinical research. We offer them in good faith, with recommendations to close inadvertent gaps in oversight and to resolve ambiguities that could lead to inconsistent application and compliance.

1. We recommend that NIH adopt a standalone section on clinical research, comparable in structure and thoroughness to Section III-C of the current NIH Guidelines, in place of the abbreviated callout currently embedded within Section IV-2 of the draft policy. Clinical research is fundamentally different from laboratory research. It involves procedural risks during the preparation and administration of investigational products that are not typically found in laboratories, and it often places unique limits on how the traditional hierarchy of safety controls can be applied. This practical variability contrasts notably with the well-controlled, contained handling typically evident in most laboratory settings. As the draft

Policy itself implicitly recognizes, the appropriate scope of oversight for clinical research differs materially from that of laboratory research. A section dedicated to clinical research would give this research the level of definition and clarity that its unique risk profile warrants and would convey its importance more fully than a brief callout does.

2. The complete scope of IBC review for clinical research in draft Policy Section IV-2 is ambiguous and can be interpreted in two distinct ways. The current text does not clearly indicate which of the interpretations NIH intended. In the first interpretation, the five general categories at the start of Section IV-2 apply to laboratory research. The clinical research callout, with its sub-bullets, sets out a separate independent, and narrower, set of criteria that apply to clinical research only. Clinical research that does not fit within this limited set of criteria in the callout is not within scope of the Policy. In the second interpretation, the five general categories apply to all research (laboratory and clinical) and the callout simply adds additional criteria specific to clinical research that IBCs are asked to consider. The clinical research callout is genuinely ambiguous as to whether it operates as the exclusive, controlling basis for IBC review of clinical research, or as an additional condition layered on top of the Policy's general scope. We ask NIH to state definitively which interpretation is intended. If NIH intends the first interpretation (which is the assumption behind most of our comments that follow), we do not believe this limited level of oversight is sufficient for clinical research, for the various reasons we set out below. If NIH intends the second interpretation, we encourage NIH to state this more clearly in the final Policy. Institutions, clinical trial sponsors, and IBCs may have difficulty resolving the correct interpretation from the currently published text alone.

3. If NIH's intention was for the clinical research callout in Section IV-2 to represent the sum total of clinical research requiring IBC oversight (see first interpretation above), we encourage NIH to reconsider and revise the Policy to adopt an equivalent degree of oversight rigor for clinical research as it applies to laboratory research. Relative to the current NIH Guidelines, the draft Policy appears to disproportionately reduce the oversight of clinical research. In doing so, it risks creating a potential oversight gap and double standard between clinical research and laboratory research. As a case in point, draft Policy Section IV-2 identifies numerous categories (bullets 1-5) of research that require IBC review and approval before initiation. In contrast, the dedicated clinical research callout embedded within Section IV-2 significantly limits the scope of research subject to IBC oversight to a handful of products that meet a small number of triggers. As a consequence, some of the exact same products (e.g., genetically modified cells and primary cells) that require IBC review in a laboratory setting would be excluded from IBC oversight in the clinical research setting on the basis that they do not meet the narrow list of criteria for oversight (i.e., they are not capable of shedding, replicating, or integrating, and do not require "higher-risk" manipulations). We do not believe this distinction in oversight requirements between laboratory and clinical research is defensible from a biosafety perspective. Moving a product from a laboratory to a clinic does not reduce the intrinsic risks of the product. If anything, handling of genetically modified products intended for administration into human research participants can introduce exposure pathways that may not exist in a contained laboratory environment, which arguably warrants equal or greater biosafety scrutiny, not less.

To illustrate the gap concretely, we describe a life cycle of an investigational product as it moves from the laboratory to the clinic. For this representative example, the product consists of chimeric antigen

receptor T (CAR-T) cells intended for intravenous administration in a clinical trial. While the product is designed, modified, formulated, and tested in the laboratory, its genetically modified characteristics would classify this as research that requires IBC review. When the identical product is shipped to a clinical site for a clinical trial, the research would now be excluded from IBC review since the CAR-T formulation meets none of the triggers (shedding, replicating, or integrating) and does not require a higher risk manipulation such as aerosolization or bladder infusion. This ignores the fact that the material and the risks to the people handling it in the clinic is the same as in the laboratory. Arguably, the steps that carry exposure potential in the clinical setting are new: receipt and storage, thawing, withdrawal of doses into syringes or infusion bags, transport through the facility from the place of preparation to the infusion area, syringe or infusion line priming, administration, and disposal of vials, syringes, infusion bags and tubing. The realistic exposure events in this scenario include needlestick injuries, splashes to the eyes or mucous membranes, aerosols generated during preparation, and spills, among others.

Since staff can be exposed to investigational products, like CAR-Ts during the entire life cycle of a clinical trial, this warrants comprehensive biosafety oversight that is not fully appreciated in the limited clinical research callout. Applying a more permissive standard to clinical research with these same products, without a clear safety-based rationale, is an inconsistency that diminishes the real risks these products present and sits uneasily alongside the draft Policy's own stated purpose of ensuring that "gold-standard science is conducted under gold-standard biosafety conditions."

We recognize that NIH may intend to make clear that once a product is administered, the research participant does not need to be contained at the same level as the product itself. We agree. A participant is not a biohazard to be contained. Our concern is different. As drafted, the callout ties oversight to the type of research (clinical versus laboratory) and not to the risk of the product and the handling steps around it. We do not believe NIH intended this loophole.

It must also be stressed that these biosafety risks in the clinical space are not adequately being addressed by other oversight bodies. Institutional Review Board (IRB) review focuses on risks to research participants and the adequacy of informed consent, and IRBs commonly rely on IBC review for biosafety assessments. The Food and Drug Administration (FDA) reviews safety, efficacy, and manufacturing quality for trial participants, but does not set biosafety precautions for clinical sites. The literature reports no consensus guidelines for healthcare workers (HCWs) handling gene therapy products (Applied Biosafety 2020, doi:10.1177/1535676020934917), and a pharmacy review notes a lack of clinical guidance from NIH, FDA, the Centers for Disease Control and Prevention (CDC), and the World Health Organization on the clinical application of gene therapy (Gene Replacement Therapy: A Primer for the Health-system Pharmacist, PMC7675776). Without IBC review, no oversight body is formally assigned to assess these handling risks further stressing the importance of maintaining comprehensive biosafety oversight of clinical research by the IBC.

A product cannot simultaneously be deemed hazardous enough in the laboratory to warrant IBC oversight, but deemed safe enough in the clinic to warrant waiving the need for IBC oversight. Such an incongruency is antithetical to responsible biosafety governance.

4. The limited scope of products subject to IBC review per the brief clinical research callout appears to exclude an entire class of products with significant biosafety implications: gene editing platforms. While some gene editing platforms are integrating, many are not. Base editors and prime editors rewrite individual bases without inserting a gene copy or other exogenous genetic material. Additionally, nucleases (e.g., CRISPR) that create double-strand DNA breaks can, when repaired by non-homologous end joining (NHEJ), disrupt a gene(s) without any integration event. These non-integrating gene editing products meet none of the clinical research callout criteria (bullets a d) and would be excluded from IBC oversight. The callout triggers might capture some viral vector-mediated gene editing products, however, they would all the miss lipid nanoparticle (LNP)-based and other non-viral editing products that are in active clinical development. We believe this is a significant gap in oversight that should be addressed.

We recognize that most editing products in clinical research today are edited ex vivo which concentrates the hazard in the laboratory and manufacturing facilities. Exposure potential to the gene editing components is lower once the final cell product reaches the clinic thus supporting less clinical research oversight using the risk-tiering model. However, the clinical field is increasingly moving toward the use of in vivo gene editing therapeutic approaches (doi.org/10.1016/j.gendis.2025.101808), in which staff are expected to handle the gene editing reagents directly. This creates a high-consequence accidental exposure risk that unquestionably requires IBC oversight. By accidental exposure we mean unintended contact between a person who is not the intended research recipient and the active editing components, such as a needlestick during preparation or administration, a splash to the eyes or mucous membranes, inhalation of aerosols during preparation or transfer, a spill during storage, thawing, or transport; and, for vehicles that are shed, contact with patient fluids or waste. The consequence of exposure depends on the delivery system, formulation, dose, and route, but ultimately, the risk is clear with potential outcomes involving irreversible changes to the genome which cannot be treated.

The risk is even more consequential when you consider the potential for germline transmission if gene editing components reach reproductive tissues. FDA asks sponsors to assess biodistribution, including to gonadal tissue, in the product's investigational application, but its genome editing guidance is directed to sponsors and to editing of somatic cells. It does not address how site staff should safely handle or secure the product exposing the gap in oversight if IBCs aren't reviewing this research. NIH has also historically declined to support grant proposals for germline alteration. By excluding IBC review of most clinical research involving gene editing, an obvious consequence is the elimination of the local IBC checkpoint that confirms that a specific protocol and its handling procedures do not create a pathway to unintended germline editing.

Lastly, gene editing reagents and delivery vehicles are dual-use technologies that can be misused requiring comprehensive governance. The draft Policy asks IBCs to determine appropriate biosafety and biosecurity measures for research (Section III-B). Excluding clinical gene editing products removes that review for the products most likely to be handled outside traditional laboratories, and it weakens the consistent institutional governance that rigorous ethical and safety standards for gene editing depend on.

We therefore recommend that NIH revise the Policy to include "gene editing" or "genetic modification" as an independent trigger for IBC review of clinical research, alongside shedding, replicating, and

integrating. This would ensure that no current or future gene editing approach falls outside IBC oversight of clinical research.

5. The limited scope of products subject to IBC review of clinical research reasonably excludes classes of recombinant and synthetic nucleic acid molecules, such as messenger RNA (mRNA) and plasmid DNA products, from IBC review. We recognize that many of these products present a comparatively low biosafety risk profile and agree that oversight should be calibrated to risk. However, the categorical exclusion of these products from IBC oversight based solely on the absence of "shedding, replicating, or integrating" properties or "higher-risk manipulation" creates a legitimate gap in safety oversight. In clinical research, mRNA- and plasmid-based products can be engineered to express biologically potent transgenes, including gene editing components, toxins, cytokines, immune modulators, constitutively active signaling molecules, engineered receptors, and other products capable of producing clinically significant biological effects and consequences from occupational exposure. The occupational exposure risks of these products are not negated simply due to the absence of "shedding, replicating, or integrating" capability. We recommend that NIH reconsider the blanket exclusion of these products from IBC oversight of clinical research. At a minimum, we recommend that NIH preserve some mechanism (e.g., delegated review) by which nucleic acid-based clinical products can be evaluated for biosafety risk (nature of the transgene involved, mechanism of action, or other biological function) rather than being categorically excluded from oversight based solely on product class.

6. We recommend that NIH clarify whether delegated review under draft Policy Section IV-3 is available for clinical research. Section IV-2 of the draft Policy has a specific callout for clinical research. By contrast, Section IV-3, which permits review by an individual or subgroup of IBC members, has no comparable callout. It is unclear whether this omission was intentional. We ask NIH to state clearly, in the final Policy or other published guidance, whether delegated review can be applied to clinical research. If it can, we encourage NIH also to clearly state which section controls when a product qualifies under both. For example, clinical research with a genetically modified Risk Group 1 (RG1) agent could presumably qualify for delegated review under Section IV-3. If that agent can replicate or shed, it could also simultaneously meet a clinical research criterion in Section IV-2 and require full IBC review. The Policy should explicitly state whether the full IBC review requirement takes precedence in cases such as this.

7. We recommend that NIH define "shedding" as used in draft Policy Section IV. The term is applied inconsistently across the biosafety and clinical research communities. Depending on the assay and detection method, "shedding" can mean detection of an infectious, transduction-competent organism (e.g., a replication-competent viral vector) or detection of non-infectious DNA fragments in patient secretions or excretions. FDA's shedding guidance defines shedding as the release of a virus- or bacteria-based gene therapy or oncolytic product from the patient through excreta, secreta, or the skin. We encourage NIH to build on that definition and to specify whether detection of non-infectious nucleic acid fragments qualifies. This distinction matters because DNA fragments alone do not necessarily indicate the presence of a viable, transmissible biohazard. An undefined term such as this could sweep low-risk products into IBC review, or exclude genuinely higher-risk ones, based on assay design rather than actual biosafety risk. Undefined shedding criteria may also result in inconsistent institutional decision-making. For example, one institution may conclude that transient detection of vector sequences by polymerase chain reaction (PCR) constitutes shedding and therefore requires IBC review of a protocol, while another

institution may require evidence of viable, infectious, or otherwise biologically active material before applying the same trigger. As a result, identical protocols could receive materially different oversight determinations depending on local interpretation. Because “shedding” is one of the clinical research criteria that determines whether a given investigational product remains within the scope of IBC review, we encourage NIH to define this term unambiguously in the final Policy, rather than leaving it open to differing institutional interpretations.

8. We recommend that NIH define “replicating” as used in draft Policy Section IV. The Policy does not specify the threshold at which a product is considered capable of “replicating.” This can create uncertainty and inconsistency in intra- and inter-institutional application of oversight. Institutions could reach different oversight determinations for products that are replication-competent, conditionally replicating, selectively replicating, helper-dependent, or single-cycle systems. What about replication-defective vectors that may be defective for replication in individuals with intact immune systems, but could be competent in immunocompromised or immunosuppressed individuals? Furthermore, to add to the ambiguity, it is unclear whether the reference to “replicating” is intended to extend beyond infectious systems to other non-infectious products such as self-amplifying RNA (saRNA), replicons, and similar technologies that replicate DNA/RNA transiently before degrading. We recommend that NIH define this term unambiguously in the final Policy to minimize variability in application. Without clearer definitions or examples, one institution may determine that IBC review is required while another exempts the same study, resulting in inconsistent oversight outcomes for equivalent biosafety risks.

We further recommend that, if NIH intended to exclude non-infectious recombinant nucleic acid products (such as saRNA and replicons) from IBC oversight, NIH reconsider and preserve a mechanism (whether through IBC review or delegated review) by which replicating nucleic acid-based clinical products can be evaluated for biosafety risk based on the unique nature of the platform and transgenes involved, rather than excluding them from any oversight based on product class alone. The literature shows that self-amplifying mRNAs have yielded replication-competent virus through a mechanism of aberrant homologous RNA recombination (doi:10.1128/mbio.02494-24). Furthermore, saRNA can drive prolonged expression and innate immune activation (PMC12469313) compared with conventional mRNA, so the consequence of an occupational exposure scales with the transgene it encodes. For these reasons, we believe saRNA and replicon systems warrant some degree of IBC review and advocate against their categorical exclusion from IBC oversight. At a minimum, we recommend that NIH preserve some mechanism (e.g., delegated review) by which these clinical products can be evaluated for biosafety risk (e.g., replication potential, nature of the transgene involved, mechanism of action) rather than being categorically excluded from oversight based solely on product class.

9. We recommend that NIH define “higher-risk manipulation” as used in draft Policy Section IV-2. The term is illustrated by example only (e.g., aerosolization, bladder infusion) and is, otherwise, left open to interpretation. The subjective nature of this term creates an effectively unenforceable standard for IBCs. “Higher-risk” is not a term with an agreed-upon standardized meaning within the biosafety community, and, absent a formal definition, different IBCs (or the same IBC evaluating different protocols over time) could reach different conclusions about whether a given manipulation procedure qualifies for IBC review. Without an objective definition or a more complete illustrative list, institutions and IBCs are likely to apply this trigger inconsistently, undermining the draft Policy’s stated goal of a predictable oversight

framework.

Additionally, the two representative examples provided for “higher-risk manipulation” refer to administration procedures only and do not address higher-risk manipulations that may occur during preparation of the product (e.g., syringe-to-syringe transfers that can create high-pressure sprays of product if the connections are not secure). Preparation of investigational products is arguably as risky as administration, if not more so, and should be equivalently considered in a definition of “higher-risk manipulation.” Given the choice of examples of higher-risk manipulation, it is unclear whether the NIH intends to apply this criteria to all clinical research procedures, or only to administration procedures. We recommend NIH clearly define their intent and include any procedure (preparation or administration) within its scope. For consideration, NIH could define the term as follows: “A higher-risk manipulation is a procedure that, based on comprehensive risk assessment of the preparation and administration procedures, creates a greater potential for exposure of personnel or contacts than can be managed through standard precautions alone. The term may include, but is not limited to, procedures that (a) generate aerosols or droplets of the product (e.g., inhalation, nebulization, or intranasal delivery), (b) place the product on a mucosal surface or in a body cavity or lumen from which release to other persons is plausible, such as intravesical instillation, or (c) can otherwise reasonably be anticipated to create splashes, sprays or spills of the biohazard that may warrant additional engineering or work practice controls.”

NIH may identify additional manipulations in accompanying guidance and should explicitly empower IBCs to designate any particular manipulation procedure as “higher-risk” based on risk assessment.

10. The draft Policy is ambiguous about whether cellular therapies manufactured ex vivo are subject to the clinical research callout. We recommend that NIH expressly clarify whether cell therapies manufactured ex vivo with integrating vectors and/or gene editing platforms fall within the scope of IBC review of clinical research. For example, CAR-T cells manufactured with lentiviral vectors or hematopoietic stem cells (HSCs) edited with clustered regularly interspaced short palindromic repeats (CRISPR) would not directly trigger any of the main criteria (“shedding, replicating, or integrating”) required for IBC oversight. This is a significant, unaddressed question that covers a widely used class of clinically relevant investigational products that are currently considered within the scope of the NIH Guidelines. Institutions attempting to resolve this ambiguity independently are likely to do so inconsistently.

Handling precautions for these products rest on two layers which address the risk of infectious disease from human-derived materials, including standard precautions and the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard. Neither of these address any novel risks created by genetic modification itself, the presence of residual replication-competent vector or gene editing components, or the hazardous nature of the transgene. FDA-approved labeling for CAR-T products also recognizes both layers. For example, the package insert for YESCARTA® (tisagenlecleucel) directs sites to employ universal precautions and also to follow local biosafety guidelines applicable for handling and disposal of the cells which have been genetically modified with a retrovirus. The IBC is the body that establishes those local guidelines. If ex vivo manufactured cell products fall outside the Policy, that labeling reference points to a governing body that no longer has an authorized role in establishing

handling guidelines for these products. We do not suggest that these products require high containment, but do ask for oversight that is proportionate to the risk. We recommend that NIH keep genetically modified cellular products within scope and make delegated review under Section IV-3 available, so that the IBC can confirm product characterization (such as vector type and replication-competent virus testing) and site handling procedures without a full committee review.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: 1. We support retaining Risk Groups (RGs) as the baseline for risk assessment. A Biosafety Level (BSL) is the containment used to work safely with an agent or product. It is a control measure, and its assignment is derived from the characteristics of the agent or product and the nature of the work proposed. The RG is a primary determinant of those characteristics, because it classifies an agent by severity of illness, route of exposure, infectious dose, rate of transmission, and availability of countermeasures. Section V-E of the draft Policy makes the same point: RGs describe the biological properties of the agent, and the appropriate BSL may be lower or higher depending on the work proposed. Section V-B likewise states that risk assessment for a genetically modified agent starts from the risks of the parent agent, which are then adjusted for the modification. Using the BSL as the baseline would start from the control measure rather than the hazard it is meant to address. The RG of the wild type organism should therefore remain the basis of risk assessment, with the BSL assigned as an outcome of that assessment.

2. We recommend that NIH state clearly whether BSL assignment by the IBC is required for clinical research conducted in clinical (non-laboratory) settings. The draft Policy acknowledges, in Section V-E, that clinical research "is most often conducted in clinical settings that do not conform to laboratory BSLs," yet stops short of stating definitively whether IBCs are required to, or not, assign a BSL to clinical research. The draft meeting minutes template and incident report template compound this ambiguity, as they both require the approved BSL containment level to be recorded. This gap is a recurring source of confusion in application due to the differences in terminology used in laboratories versus clinical environments which do not traditionally use BSLs in practice.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): We support the draft Policy's encouragement of voluntary compliance by entities not otherwise subject to it, such as non-NIH-funded institutions. Biosafety oversight protects staff, the surrounding community, and the environment from risks that do not depend on the source of an institution's funding. It helps institutions without federal funding adopt recognized best practices for risk assessment, containment, training, and incident response. It also promotes consistency, because research conducted to a common standard is easier to compare, oversee and trust. Products that move between funded and unfunded settings are also then handled under comparable safeguards. Voluntary adoption can also build a culture of biosafety that carries forward if an institution later receives NIH funding. We encourage NIH to support voluntary adopters by making the Policy's templates, definitions, and implementation resources publicly available and easy to use.

We encourage NIH to go further for institutions that are not subject to the Policy by adding educational and outreach resources, such as webinars, frequently asked questions, and short training modules written for institutions without an existing biosafety program to illustrate the value of biosafety governance. Other options include guidance on how an institution without an IBC can obtain oversight

through shared or collaborative arrangements, and a simple voluntary way to signal adoption, such as public recognition of institutions that follow the Policy. Making voluntary participation easy and visible would extend consistent biosafety governance to research outside NIH funding.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1. We support NIH's intent to promote transparency and public accountability through the public posting of incident reports. That said, we respectfully raise a concern that this requirement, as currently structured, may have an unintended consequence that runs counter to its own goal of consistent and faithful incident reporting. Individuals who are aware that an incident involving them personally will be posted to a public-facing website may become less willing to report that incident (whether out of concern for their own privacy, professional reputation, or standing with their employer), which in turn could delay or discourage them from seeking appropriate medical attention or triggering a timely institutional response. We encourage NIH to consider additional reporting safeguards that would preserve transparency while minimizing any resistance to frontline reporting. Specific safeguards, and a proposed standard for what should and should not appear in publicly posted reports, follow below.

2. We recommend that NIH clearly specify, in the final Policy or in the templates, what information should not appear in publicly posted incident reports and what information should. We offer the following starting point for consideration. Information that should not be posted includes: (a) names or other identifying details (e.g., position titles) of principal investigators and staff, including any other detail that would reasonably allow a person to be identified at a small site through title, role, dates, or a combination of descriptors; (b) personal health information, including diagnoses, treatment, test results, and follow-up for any individual; (c) location detail that could create a security or safety risk, such as building name or room number; and (d) sponsor-confidential or proprietary information, such as investigational product descriptions. Information that is useful to the public and supports learning from incidents includes the type of incident and the agent category and Risk Group; the setting (BSL) and the activity being performed during the incident; whether an overt exposure occurred, by what route, and what response followed; and the root cause and the corrective and preventive actions taken.

The following two scenarios illustrate situations that show why careful consideration of what information is included in an incident report matters. Scenario 1: A needlestick occurs while one pharmacist prepares a study dose in a small hospital pharmacy. A posted report that identifies the role ("pharmacist") and the date easily identifies the employee if there's just one pharmacist working on that day. Scenario 2: A splash to the eye occurs while a graduate student is manipulating an agent in a laboratory. The laboratory is small and has just one graduate student and a technician. A posted report that identifies the role ("graduate student") and the date would likewise identify the employee. As noted previously, staff who anticipate potential for their identification may delay or avoid reporting.

3. We recommend for consideration the following five safeguards, which would preserve transparency while protecting reporters, participants, and security: (i) a two-tier format, in which the full report goes to the IBC and NIH and the public version is a standardized, de-identified summary generated from the same template, with each template field designated as public or restricted; (ii) a single national redaction standard based on the lists above, applied uniformly, with worked examples of acceptable and unacceptable postings published by NIH; (iii) summary-level or aggregate posting where small numbers could identify a person, for example at sites with few staff; (iv) a confidential reporting pathway for

individuals to the IBC or biological safety officer, together with a statement that the public version will be de-identified and that reporting is protected from retaliation; and (v) review of the public version by the IBC or its administrator before posting. NIH could also use its planned Annual Incident Summary Report (Section III-D) and the voluntary confidential near-miss reporting channel to the National Biosafety Data and Safety Analysis Center (Section III-C) to share lessons learned without institution-level detail.

6. Other feedback relevant to this resource: 1. It is not clear whether the Biosafety Assurance requirement, including the biosafety policies and procedures that support it, can be fulfilled by an externally administered IBC on behalf of the institutions it serves. We recommend that NIH state explicitly, in the final Policy or in subsequent guidance, that it can. We believe this is sound for the following reasons. The Biosafety Assurance requirement, as drafted, may create challenges for institutions that exclusively rely on externally administered IBCs to support their biosafety oversight obligations. Community hospitals and clinics, private practices, rural research sites, and other smaller institutions frequently depend on externally administered IBCs because they lack the expertise or resources to maintain a fully constituted internal IBC and biosafety program. Many of these institutions are unlikely to have independently developed the biosafety policies, procedures, and supporting documentation that the Assurance appears to mandate. Requiring each such institution to develop this documentation independently, from scratch, would impose a significant, and in many cases disproportionate, compliance burden without materially improving biosafety outcomes. Allowing their externally administered IBC provider to furnish these documents for them removes this barrier. Furnishing documents does not, by itself, ensure that an institution follows them. We therefore suggest that NIH require, as a condition of approving a Biosafety Assurance that relies on externally furnished documents, a documented attestation that the institution will follow the policies and procedures supplied by its externally administered IBC. However, we also do recognize NIH's parallel effort to reduce regulatory burden. To avoid another institutional attestation, NIH could instead make this commitment a term and condition of funding awards. Either way, the Assurance would reflect both the existence of appropriate biosafety documentation and the institution's commitment to follow it.

2. The requirement to host and continually update public postings (the IBC roster, meeting minutes, and incident reports) applies to every institution, but the burden of meeting that requirement varies widely with an institution’s available resources. Universities and large academic medical centers often have the web infrastructure, IT staff, and financial resources to meet this requirement. Smaller institutions, including rural practices, community clinics, and individual sites within larger networks may have few or none of these resources, so the same compliance requirement can impose a disproportionate burden. We see two ways to address this and support either. Option 1 lets institutions that contract with an externally administered IBC have that IBC meet the posting requirements on their behalf. Option 2 has NIH establish and host a single, centralized system for submitting and publicly posting IBC records.

Option 1. We recommend that NIH explicitly permit externally administered IBCs to host required public-facing postings (the IBC roster, meeting minutes, and incident reports) on behalf of the institutions they serve, rather than requiring each institution to build and independently maintain this capability. This flexibility would be particularly important for institutions that are not well positioned to build and maintain the IT infrastructure themselves (e.g., rural practices and small community clinics). Based on our experience administering IBCs for a diverse range of institution types, we see recurring financial, technical, operational, logistical, and legal barriers for some institutions to maintain a continually

updated public-facing website:

a. From a cost standpoint, rural and community practices, small physician offices, and similar non-academic institutions often use a website that was built as a one-time, basic marketing expense and lack the operating budget to update it promptly and repeatedly after each IBC meeting or reportable incident.

b. Technically, many of these institutions often have no in-house web development or IT staff or standing vendor relationship, and their websites were not designed to support recurring, structured regulatory postings. Third-party vendors commonly handle updates through formal change-request processes, which can delay postings beyond the Policy's timelines (e.g., posting minutes promptly after approval, or incident reports within 30 days). The five-year minimum posting requirement makes this an ongoing content management and retention burden, which compounds over time for institutions without a scalable web management process.

c. Logistically, institutions that are part of larger, multi-site or multinational networks may have no authority, access, or technical means to modify the entire corporate public-facing website governing the network as a whole. A single site conducting research subject to the Policy may depend on a centralized corporate or franchise structure that was not built to accommodate this specific compliance need.

d. From a legal standpoint, multinational site networks may host their website on a platform or domain governed by non-U.S. data privacy or content regulations (e.g., the General Data Protection Regulation, or GDPR), which may require an additional level of legal review before certain clinical trial content can be posted which can affect compliance with the Policy's timelines. Separately, in clinical research, it is often the trial sponsor that holds the direct funding relationship with the NIH and not the individual trial sites (institutions). Non-funded sites may legally challenge their obligation to update their websites to satisfy the sponsor's compliance obligations which can pose a significant barrier to IBC compliance with the public-facing postings

Centralizing postings with a qualified external IBC administrator which has the subject-matter expertise, infrastructure, and operational capacity to manage them consistently and in compliance with the Policy's redaction, posting, and timing requirements, would materially reduce these burdens while preserving the transparency the Policy is intended to achieve. We would further note that this approach is not merely a burden-reduction measure for institutions; it would likely advance NIH's own transparency and compliance objectives more effectively than the current site-by-site model. A single, centralized location maintained by a qualified external IBC administrator would be more consistently accurate, complete, and up to date than dozens or hundreds of independently maintained institutional websites that differ in format and resources, and would allow the public, researchers, and NIH itself to locate and review IBC rosters, meeting minutes, and incident reports for all covered institutions in one place, rather than needing to identify and navigate each institution's individual website. We believe centralization of records with the externally administered IBC would result in materially greater public transparency and easier public access to these records than the current, fully decentralized posting model contemplated by the draft Policy, while also making compliance considerably easier for NIH to monitor.

Option 2. As an alternative, or as a complement, NIH could establish and host a centralized system for the submission and public posting of IBC rosters, meeting minutes, and incident reports. This would create a nationally universal repository of IBC records for all institutions, whether their IBC is internal or externally administered. Institutions would submit records once, using the NIH templates, and the system would apply the redaction standard consistently and post the public version. Benefits include a single searchable location for the public, researchers and NIH; uniform formatting and redaction; no need for each institution to build or maintain a website; easier NIH monitoring of compliance and trends, including through the Annual Incident Summary Report; and lower cost and burden across the research enterprise. NIH would retain policy control and could set requirements for data security, privacy protection, institutional review before posting and independent oversight of the operator.

3. We recommend that NIH provide guidance on how intermediate-size and large-size population expanded access protocols are intended to be treated under the Policy. The draft Policy addresses individual-patient expanded access use under an FDA-regulated IND application as being outside the scope of IBC review, but does not address other forms of expanded access protocols that are also common (e.g., intermediate- and large-population protocols). We request that NIH clarify how these other forms of expanded access are intended to be treated differently, if at all, relative to individual-patient use to avoid confusion and inconsistent oversight from institution to institution.

4. If NIH intends to narrow the clinical research scope, we recommend that NIH issue clear guidance on how IBCs should manage the transition of oversight for clinical studies that are currently within the scope of IBC review under the current NIH Guidelines, but would fall outside the narrower scope of the Policy once it takes effect. The guidance should address at minimum (i) whether and how active protocols may transition out of IBC oversight; (ii) how continuity of biosafety oversight is handled for participants already enrolled; and (iii) how the transition is managed and documented. We encourage NIH to provide this direction rather than leave it to individual institutions and IBCs to resolve independently, which risks inconsistent implementation and avoidable gaps in oversight during the transition.

5. We recommend that NIH replace the award-linked retention period for IBC minutes and incident reports with a fixed maximum period. Draft NIH Policy Section III-A ties IBC records to Section 8.4.2 of the NIH Grants Policy Statement, which requires retention for three years after an award's final financial report, and minutes and incident reports must also be posted for at least five years. For a five- or ten-year center grant, public availability could therefore far exceed five years. At most institutions, IBCs generally do not know every award that supports a given protocol or when each award closes, and their document management systems are typically not designed to track this. To further compound the complexity, with this new requirement, the system would need to be able to crosslink protocols that may simultaneously be tied to several principal investigators and several grants, or grants that transfer with an investigator departing to another institution. Linking IBC records to grants would require significant financial investment and operational effort and, depending on system design, a complete IT system rebuild.

The Policy would also need to address how non-funded institutions are to navigate the award-linked retention period when the institution has no visibility to the grant funding timelines. This would be

particularly relevant for clinical research sponsored by funded entities ("Sponsors") and conducted at non-funded trial sites. Similarly, externally administered IBCs are independent of the institutions they serve and do not hold or have access to their grant records. It cannot see when an institution's awards are renewed, extended, transferred or closed, so it has no means to link its records to NIH award timelines. Only the institutions themselves hold that information creating a significant barrier to this drafted compliance requirement.

Given these likely hurdles to compliance, we recommend a fixed period measured from the date of posting, such as five years, which matches the minimum already in the draft Policy. Institutions would remain responsible for retaining records under the Grants Policy Statement. If NIH keeps an award-linked approach, we ask that NIH provide a sufficiently long implementation period to allow for all manner of institutions to rebuild their systems to facilitate compliance with this new mandate.

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Description: Comments Cover Letter

National Institutes of Health
Office of Science Policy

Re: NOT-OD-26-112 Draft NIH Biosafety Policy for Research Involving Biohazards

October 19, 2026

Dear NIH Office of Science Policy,

Sabai appreciates the opportunity to provide input on the National Institutes of Health's (NIH) draft policy on Biosafety for Research Involving Biohazards. Sabai operates in the clinical research space specializes in providing biosafety and human research protections through provision of independent Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) services. We acknowledge the efforts of the NIH to modernize biosafety practices across biomedical research efforts, given the ever-shifting landscape of modern science. We also appreciate the goal of NIH to strengthen the role of IBCs in biosafety regulation. This letter accompanies our comment form responses and summarizes our principal recommendations.

Scope of Clinical Research Oversight:

As currently written, Section IV of the policy can be interpreted in two vastly different ways. First, that clinical research **only** requires review and oversight if it satisfies the specific callouts found in Section IV-2. Second, that Section IV applies to all research, spanning from basic to clinical, and that **in addition**, clinical research has a specific set of risks outlined in Section IV-2 beyond those captured by other sections. Institutions, clinical trial sponsors, and IBCs may have difficulty resolving NIH's intention from the published text alone. **Sabai recommends that NIH revise this section to clearly establish that clinical research is subject to the same level of oversight as laboratory research, with additional conditions as outlined in Section IV-2.**

If NIH does intend to reduce the scope of clinical research subject to IBC oversight, **we believe this will lead to an insufficient level of oversight**. Carving out clinical research from oversight requirements and narrowing the scope to only reviewing products capable of shedding, replicating, or integrating, or the requirement of "higher risk" manipulations creates an oversight gap and double standard between clinical research and laboratory research. Some examples of resulting biosafety risk include:

- Certain products that require IBC review in a laboratory setting (e.g., genetically modified cells, primary cell lines) would be excluded from IBC oversight. Moving a product from a laboratory to a clinic does not reduce the intrinsic risks of the product. Administering a genetically modified product to a human research participant may introduce novel exposure pathways that do not exist in a contained laboratory environment, which arguably warrants equal or greater biosafety scrutiny, not less. Applying a more permissive standard to clinical research with these same products, without a clear safety-based rationale is an inconsistency that diminishes the real risks these products present.
- The limited scope of products subject to IBC review per the brief clinical research callout appears to exclude an entire class of products with significant biosafety implications: gene editing platforms. Given the increasing prevalence of in vivo gene editing therapeutic approaches and the corresponding risks of exposure events leading to irreversible genomic alterations, we believe the absence of oversight for this product class is not commensurate with the risks these products pose. Furthermore, given the potential for germline transmission and alteration, and dual-use misuse of the technology, gene editing requires rigorous ethical and safety standards and biosafety governance, not less as the draft Policy would support.

- The limited scope of products subject to IBC review of clinical research would exclude classes of recombinant and synthetic nucleic acid molecules, such as mRNA and plasmid DNA products, from IBC review. We recognize that many of these products present a comparatively low biosafety risk profile and agree that oversight should be appropriately calibrated to risk. However, their categorical exclusion based solely on the absence of "shedding, replication, or integration" properties or "high-risk manipulation" creates a legitimate gap in safety oversight. The occupational exposure risks of these products are not negated simply due to the absence of "shedding, replication or integration" capability. If NIH plans to exclude this research from oversight, the policy should preserve some mechanism (whether through IBC review, delegated review, or another appropriate pathway) by which nucleic acid-based clinical products can be evaluated for biosafety risk rather than being excluded from oversight completely.
- Cellular therapies manufactured ex vivo with integrating vectors and/or gene editing platforms may fall outside the scope of clinical research oversight. For example, chimeric antigen receptor T (CAR-T) cells manufactured with lentiviral vectors or CRISPR-edited hematopoietic stem cells (HSCs) would not directly trigger any of the main criteria ("shedding, replicating, or integrating") required for IBC oversight. This exclusion would cover a widely used class of common, clinically-relevant investigational products that currently are considered in scope of the NIH Guidelines. In the absence of IBC oversight, no other governing body is currently positioned to evaluate the risks created by genetic modification.

If NIH does intend to narrow the clinical research scope, we recommend that **NIH issue clear, consistent guidance addressing how local and externally administered IBCs should manage the transition of oversight for clinical studies that are currently within the scope of IBC review under the current NIH Guidelines, but that would no longer meet the narrower clinical research scope described in Section IV-2 once the final Policy takes effect.** We recommend that this guidance address, at minimum: (i) whether and how currently active protocols may transition out of IBC oversight, (ii) how continuity of biosafety oversight should be handled for research participants already enrolled at the time of transition; and (iii) how the transition period itself should be managed and documented. Clear transition expectations would promote continuity of biosafety oversight, preservation of institutional knowledge, uninterrupted access to study records, and consistent management of participant safety issues that may emerge after enrollment.

Use of External IBCs:

We recommend that NIH explicitly permits externally administered IBCs to furnish the biosafety policies and procedures required to support an institution's Biosafety Assurance on behalf of the institutions they serve. Community hospitals and clinics, physician practices, rural research sites, and other smaller institutions frequently depend on external IBCs because they lack the expertise and/or resources necessary to maintain a fully constituted internal IBC and associated biosafety program. We believe requiring institutions to write their own policies and procedures from scratch would create unnecessary barriers without materially improving biosafety outcomes. Allowing the externally administered IBC provider to furnish the biosafety policies, procedures, and other supporting documentation on behalf of the institutions it serves would avoid this heavy burden and eliminate the compliance gap.

We recognize, however, that furnishing these documents alone does not ensure that the institution will actually adhere to them in practice. We therefore suggest that NIH require, as a condition of an Assurance that relies on externally furnished documentation, a documented attestation from the institution acknowledging that it will follow the biosafety policies and procedures supplied by its externally administered IBC. Alternatively, we would also support an attestation of this nature to be incorporated into the terms and conditions of awards, reducing regulatory burden while maintaining biosafety gold-standard practices.

Further, we recommend that **NIH explicitly permit externally administered IBCs to host required public-facing postings (the IBC roster, meeting minutes, and incident reports) on behalf of the institutions they serve, rather than requiring each institution to build and independently maintain this capability.** This flexibility

would be particularly important for institutions that are not large universities or major academic medical centers and that may not be well positioned to build and maintain the IT infrastructure themselves (e.g., rural practices and small community clinics). Centralizing these postings with a qualified external IBC administrator, an entity with the subject-matter expertise, infrastructure, and operational capacity to manage them consistently and in compliance with the Policy's redaction, posting and timing requirements, would materially reduce these burdens for institutions while preserving the transparency the Policy is intended to achieve.

As an alternative or a complement, NIH could establish and host a centralized system for the submission and public posting of IBC rosters, meeting minutes, and incident reports. This would create a nationally universal repository of IBC records for all institutions, whether their IBC is internal or externally administered.

Use of Risk Groups (RGs) as a Baseline for Risk Assessment:

We support retaining RGs as the baseline for risk assessment. However, we recommend **that NIH clearly state whether biosafety containment level (BSL) assignment by the IBC is required for clinical research conducted in clinical (non-laboratory) settings.** The draft Policy acknowledges, in Section V-E, that clinical research "is most often conducted in clinical settings that do not conform to laboratory BSLs," yet stops short of stating definitively that IBCs are not required to assign a BSL to clinical research. The draft meeting minutes template and incident report template compound this ambiguity, as they both require the approved BSL containment level to be recorded. This gap is a recurring source of confusion in application due to the differences in terminology used in laboratories versus clinical environments.

Definitions:

We recommend that NIH more clearly define "shedding," "replicating," and "higher-risk manipulation," as used in Section IV-2. Without objective definitions, institutions and IBCs are likely to interpret these terms inconsistently, undermining the draft Policy's stated goal of a predictable oversight framework.

- **Shedding:** This term is applied inconsistently across the biosafety and clinical research communities. Depending on the assay and detection method used, "shedding" can refer either to detection of an infectious, transduction-competent organism (e.g., a replication-competent viral vector) or to detection of non-infectious DNA fragments in patient secretions or excretions. This distinction matters since the presence of DNA fragments alone does not necessarily indicate the presence of a viable, transmissible biohazard. An undefined term such as this could sweep low-risk products into IBC review, or exclude higher-risk ones, based on assay design rather than actual biosafety risk. Undefined shedding criteria may also result in inconsistent institutional decision-making. As a result, identical protocols could receive materially different oversight determinations depending upon local interpretation.
- **Replicating:** As drafted, the Policy does not specify the threshold at which a product is considered capable of "replicating." This can create uncertainty and inconsistency in intra- and inter-institutional application of oversight given that different definitions of "replication" could be applied depending on whether a product is fully replication-competent, conditionally-replicating, selectively-replicating, helper-dependent, or is a single-replication cycle system. Furthermore, to add to the ambiguity, it is unclear whether the reference to "replicating" extends beyond infectious systems to other products such as self-amplifying RNA (saRNA), replicons, and similar technologies that replicate DNA/RNA transiently before degrading.
- **Higher-risk manipulation:** As drafted, the term is illustrated only by example (e.g., aerosolization, bladder infusion) and is otherwise left open to subjective interpretation. The subjective nature of this term creates an unenforceable standard for IBCs. "Higher-risk" is not a term with an agreed-upon standardized meaning within the biosafety community, and, absent a formal definition, different IBCs (or the same IBC evaluating different protocols over time) could reasonably reach different conclusions about whether a given manipulation procedure qualifies.

Incident Report Posting:

We support NIH's intent to promote transparency and public accountability through the public posting of incident reports. That said, we respectfully raise a concern that this requirement, as currently structured, may have an unintended consequence that runs counter to its own goal of consistent and faithful incident reporting. Individuals who are aware that an incident involving them personally will be posted to a public-facing website may become less willing to report that incident (whether out of concern for their own privacy, professional reputation, or standing with their employer), which in turn could delay or discourage them from seeking appropriate medical attention or triggering a timely institutional response. **We encourage NIH to consider additional reporting safeguards that would preserve transparency while minimizing any resistance to frontline reporting.** Specific safeguards, and a proposed standard for what should and should not appear in publicly posted reports, follow below.

Thank you for your consideration of our comments. For questions, please feel free to reach out to me at gcoulson@sabaiglobal.com.

Garry Coulson, PhD
Senior Director, Institutional Partnerships & Biosafety Advisor
Sabai Global

440. University of Mississippi

I am responding: On behalf of an organization

Name:

Name of Organization: University of Mississippi

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: a. Clarify the policy's boundaries

We appreciate NIH's effort to describe the research covered by the policy. A definition of "biohazard" would help institutions apply that scope consistently. The draft describes biomedical research in laboratory settings and combines a human-health risk threshold with selected categories of materials. It is less clear how institutions should treat materials that principally affect animals, plants, agriculture, or the environment, particularly given the provisions calling for IBC assessment of environmental and population effects.

We ask NIH to clarify whether these risks fall within this policy, remain outside its scope, or are addressed through another federal framework. This clarification would help institutions avoid both gaps and unnecessary duplication in oversight.

b. Calibrate toxin and protein oversight to meaningful risk

We support appropriate oversight of biological toxins and disease associated proteins. As written, however, the draft appears to cover all toxins and require delegated review of non-Select Agent toxin proteins without thresholds for quantity, potency, concentration, or activity. References to "prions and other self-aggregating proteins" may also be interpreted more broadly than the disease-associated definition.

Please consider distinguishing biological toxins from other hazardous proteins, addressing inactive derivatives, subunits, and nucleic acids encoding toxins, and establishing risk-based thresholds or exemptions. Limiting the self-aggregating protein category to transmissible or experimentally propagating disease associated materials would also help focus review on meaningful biosafety risks.

c. Clarify expectations for primary cells and established cell lines

Additional guidance on “adventitious agents” would be especially helpful. The term appears in Section IV-2’s requirement for IBC approval of research with primary cells that may be contaminated, in Section V-A’s discussion of primary cells and tissues, and in the incident reporting exception for certain post-exposure treatment.

Without a definition or examples, institutions may interpret “may be contaminated” to include nearly all primary cell work, including cells from low risk sources. It is also unclear how this provision relates to Section II’s scope and Section IV-3’s delegated review of well characterized cell lines. We would welcome a definition and examples that distinguish materials requiring full committee review, delegated review, or no review, and explain how to apply the reporting exception consistently.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): a. Explain how overlapping review categories apply

We welcome the use of tiered review to align oversight with risk. Sections IV-2 and IV-3 would benefit from a clear rule for activities that appear to fit both categories. Genetically modified cells, viruses, and organisms appear in the full committee category, while subsets of that work appear in the delegated category.

Please consider stating expressly that the most specific category controls and providing a decision table with examples of full committee review, delegated review, registration, exemption, and NIH review. This would support consistent decisions across institutions.

b. Provide streamlined pathways for routine minimal risk activities

We encourage NIH to consider exemptions or administrative registration for activities that a documented institutional screening process determines present minimal biosafety risk. Examples include commercial transgenic animals maintained at ABSL-1, low risk plasmids, replication-incompetent non-integrating vectors expressing low risk transgenes, well characterized cell lines, and genetically modified RG1 organisms.

Allowing these pathways, with institutional discretion to elevate review when local circumstances warrant, would help preserve IBC capacity for higher risk activities while retaining appropriate institutional oversight.

3. Continued utility of Risk Groups: a. Distinguish genetic engineering from other forms of change

We appreciate the intent to account for changes that may affect an organism’s risk. The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means, which could also bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory review without a demonstrated increase in biosafety risk.

We ask NIH to distinguish deliberate genetic engineering from these other processes and calibrate oversight to the resulting phenotype and risk. Examples would help institutions determine when an

activity changes the level of oversight required.

b. Support consistent risk assessment and containment decisions

We support the emphasis on risk assessment and mitigation. Institutions would benefit from practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk.

We also encourage NIH to retain a clear distinction between Risk Group (RG), which describes agent characteristics, and Biosafety Level (BSL) and Animal Biosafety Level (ABSL), which describe containment. Guidance explaining how these classifications inform, but do not substitute for, activity-specific risk assessment would be valuable.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): a. Explain how overlapping review categories apply

We welcome the use of tiered review to align oversight with risk. Sections IV-2 and IV-3 would benefit from a clear rule for activities that appear to fit both categories. Genetically modified cells, viruses, and organisms appear in the full committee category, while subsets of that work appear in the delegated category.

Please consider stating expressly that the most specific category controls and providing a decision table with examples of full committee review, delegated review, registration, exemption, and NIH review. This would support consistent decisions across institutions.

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Allowing these pathways, with institutional discretion to elevate review when local circumstances warrant, would help preserve IBC capacity for higher risk activities while retaining appropriate institutional oversight.

3. Risk Assessment and the Continued Utility of Risk Groups

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We also encourage NIH to retain a clear distinction between Risk Group (RG), which describes agent characteristics, and Biosafety Level (BSL) and Animal Biosafety Level (ABSL), which describe containment. Guidance explaining how these classifications inform, but do not substitute for, activity-specific risk assessment would be valuable.

4. Roles, Responsibilities, Compliance, and Transparency

a. Establish a clear foundation for IBC authority and independence

We support the requirement for an IBC and encourage NIH to pair its responsibilities with explicit institutional authority, support, and independent decision making. An “Establishing an IBC” subsection could provide a consistent foundation while allowing flexibility in institutional structure. We offer the following language for consideration:

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

b. Distinguish substantive oversight from administrative support

Clearer separation of IBC oversight functions, committee procedures, and administrative tasks would help institutions assign work appropriately and support timely responses. Please consider specifying that the IBC’s substantive responsibilities include:

Reviewing the biosafety program, including practices, training, emergency preparedness, and continued compliance.

Conducting or directing periodic, risk-based evaluations of facilities, equipment, and containment, with findings, deficiencies, and reasonable corrective plans and schedules reported to the Institutional Official or designee.

Reviewing concerns, incidents, unsafe conditions, and noncompliance; requiring corrective measures; overseeing resolution; and recommending improvements to facilities, training, and resources.

Approving, requiring modifications to secure approval, or withholding approval of covered activities and significant changes before implementation.

Suspending or withdrawing approval and requiring cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

We also encourage flexibility for qualified staff to conduct evaluations under written institutional procedures, with intervals proportionate to risk and IBC responsibility retained for oversight determinations. The IBC would approve its minutes and substantive determinations, while staff could prepare, retain, redact, and post records; communicate decisions; track deadlines; and prepare authorized submissions.

Please also clarify immediate stop-work authority and subsequent IBC review. Qualified response teams need to be able to investigate and take immediate protective action without waiting for a committee meeting.

c. Align accountability with authority

The expanded responsibilities assigned to BSOs and IBCs would be more effective if accompanied by explicit access to facilities and relevant records, direct reporting and escalation pathways, and authority to require corrective measures and stop or suspend unsafe work when necessary. We ask NIH to make these authorities clear so that institutional personnel can fulfill the responsibilities the policy assigns to them.

d. Support experienced program leadership

We appreciate the draft's recognition of the Biological Safety Officer's role. Where BSO duties are assigned to another official, equivalent qualifications and institutional support remain essential.

Please consider requiring each covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to its research portfolio. Expectations for qualifications, institutional access, reporting relationships, resources, and escalation of unresolved risks would help institutions establish effective leadership. An official performing BSO duties would need equivalent qualifications for those duties.

Guidance on the relationships among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official would also be helpful. In particular, institutions would benefit from clarification of which roles may be combined, how independence is protected, and whether the BSO's IBC role includes program administration in addition to voting membership. We encourage NIH to emphasize experience and functional authority, comparable to other institutional oversight leaders such as animal welfare directors or institutional veterinarians, while allowing flexibility in titles and administrative placement.

e. Clarify occupational health and safety expectations

We welcome the recognition of occupational health and safety as part of an effective biosafety program. The draft notes that other regulations and policies may require an Occupational Health and Safety Program. Clear triggers, assigned authorities, and responsibility for developing and communicating required procedures would help institutions understand and coordinate these obligations.

f. Clarify committee governance

Additional guidance on quorum and voting would support consistent committee decisions. We ask NIH to specify that a member recused because of a conflict does not count toward the quorum for that matter and to explain the voting denominator after recusal.

Institutions would also welcome expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

g. Map retention requirements to record types

A record retention table would be a practical aid to implementation. Please consider including protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. Identifying the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements would reduce uncertainty and inconsistent practice.

h. Provide a predictable Biosafety Assurance process

We appreciate the value of an institutional Biosafety Assurance and ask NIH to provide a standardized template and a predictable submission, approval, and renewal process. These resources would promote consistent submissions and help prevent interruptions during timely renewal.

A template could distinguish required, conditional, and optional fields and address institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. We encourage NIH to retain substantive obligations in the policy itself rather than introduce additional requirements through templates.

Please also specify required institutional signatures, the submission system, completeness criteria, and how timely renewals will be handled while NIH review is pending. Clarifying which information must be public and which may be submitted directly to NIH when public posting is inappropriate or unavailable would further support implementation.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: a. Preserve local management of lower risk events

We support reporting that enables NIH to identify significant risks and strengthen biosafety. Please consider preserving local IBC management of lower risk events and near misses, without requiring public posting of every internally reviewed minor event or unredacted identifying information. A proportionate approach would support prompt reporting and corrective action while focusing federal reporting on events that warrant that level of oversight.

b. Use aggregate reporting to advance transparency and learning

UM supports appropriate transparency regarding biosafety incidents. We ask NIH to consider whether the proposed public information, even when direct identifiers are removed, could identify individuals through contextual details and raise concerns about disclosure of protected medical information. In areas that have historically attracted harassment or threats, including animal research, public disclosure of investigator identities, funding information, or other identifying details may also create risks for researchers and animal care personnel.

We encourage NIH to meet its transparency goals through aggregated, de-identified incident data, including an Annual Incident Summary Report and the National Biosafety Data and Safety Analysis Center (NBDSAC). Annual summaries of trends, contributing factors, and lessons learned could support shared learning without identifying individuals or institutions in routine, well managed incidents. Full records could remain available to NIH and other authorized reviewers for investigations of laboratory-acquired infections and other public health purposes.

For a voluntary learning system to be effective, institutions and researchers need to understand its confidentiality protections, disclosure boundaries, and relationship to enforcement. Clear parameters would help build confidence in participation and improve the usefulness of the information collected.

c. Explain how investigator duties and reporting pathways interact

Section III-C assigns investigators safe research responsibilities that intersect with institutionally managed facilities and services. We would welcome clarification of how these responsibilities are shared so investigators understand which actions they must take directly and which require institutional coordination.

Please also explain how confidential voluntary reporting to NBDSAC interacts with mandatory NIH reporting and public posting. Clear limits on confidentiality and a clear distinction between voluntary

learning submissions and required reports would help institutions participate with an accurate understanding of their obligations.

6. Other feedback relevant to this resource: a. Provide practical implementation resources

We appreciate NIH's efforts to support institutions through this transition. The following resources would be particularly valuable before implementation begins:

A Biosafety Assurance template and model institutional policies.

Decision trees, risk assessment forms, and worked examples.

Training materials for IBC members, BSOs, PIs, and staff.

Sample completed minutes and incident reports, with clear redaction guidance.

A national Risk Group and containment determination database.

Guidance for external, shared, and consortium IBC models.

Making these resources available with the final policy would help institutions develop consistent procedures and avoid repeated revisions as expectations become clearer.

b. Allow sufficient time for a coordinated transition

Implementing the proposed policy will require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research. We respectfully request at least 12 months for full implementation after final guidance and required templates are available.

Please consider staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, allowing conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher risk work, would help institutions manage the transition effectively. Preserving staggered renewal cycles would also reduce avoidable backlogs.

Uploaded File: UM-Comments-NIH-Draft-Biosafety-Policy.docx

Description: University of Mississippi's Response to NIH NOT-OD-26-112

University of Mississippi's Response to NIH's Draft Biosafety Policy for Research Involving Biohazards

Response to NOT-OD-26-112

The University of Mississippi (UM) appreciates the opportunity to comment on NIH's Draft Biosafety Policy for Research Involving Biohazards. We support NIH's commitment to protecting human health and the environment and appreciate its efforts to engage researchers, institutions, and community members in developing a clearer, more accessible policy. Our IBC has participated in NIH's listening sessions and attended webinars hosted by BSAA, ABSA, CSHEMA, and COGR to better understand the proposed changes and their implications for our research community.

We share the goal of strengthening biosafety oversight through requirements that are clear, proportionate to risk, and practical to implement. In that spirit, we offer the following recommendations to help institutions apply the policy consistently and direct resources toward activities with the greatest potential risk.

1. Scope of Research Covered by the Policy

a. Clarify the policy's boundaries

We appreciate NIH's effort to describe the research covered by the policy. A definition of "biohazard" would help institutions apply that scope consistently. The draft describes biomedical research in laboratory settings and combines a human-health risk threshold with selected categories of materials. It is less clear how institutions should treat materials that principally affect animals, plants, agriculture, or the environment, particularly given the provisions calling for IBC assessment of environmental and population effects.

We ask NIH to clarify whether these risks fall within this policy, remain outside its scope, or are addressed through another federal framework. This clarification would help institutions avoid both gaps and unnecessary duplication in oversight.

b. Calibrate toxin and protein oversight to meaningful risk

We support appropriate oversight of biological toxins and disease-associated proteins. As written, however, the draft appears to cover all toxins and require delegated review of non-Select Agent toxin proteins without thresholds for quantity, potency, concentration, or activity. References to "prions and other self-aggregating proteins" may also be interpreted more broadly than the disease-associated definition.

Please consider distinguishing biological toxins from other hazardous proteins, addressing inactive derivatives, subunits, and nucleic acids encoding toxins, and establishing risk-based thresholds or exemptions. Limiting the self-aggregating protein category to transmissible or experimentally propagating disease-associated materials would also help focus review on meaningful biosafety risks.

c. Clarify expectations for primary cells and established cell lines

Additional guidance on "adventitious agents" would be especially helpful. The term appears in Section IV-2's requirement for IBC approval of research with primary cells that may be contaminated, in Section V-A's discussion of primary cells and tissues, and in the incident-reporting exception for certain post-exposure treatment.

Without a definition or examples, institutions may interpret "may be contaminated" to include nearly all primary cell work, including cells from low-risk sources. It is also unclear how this provision relates to Section II's scope and Section IV-3's delegated review of well-characterized cell lines. We would welcome a definition and examples that distinguish materials requiring full committee review, delegated review, or no review, and explain how to apply the reporting exception consistently.

2. Tiered Oversight and Calibration to Risk

a. Explain how overlapping review categories apply

We welcome the use of tiered review to align oversight with risk. Sections IV-2 and IV-3 would benefit from a clear rule for activities that appear to fit both categories. Genetically modified cells, viruses, and organisms appear in the full committee category, while subsets of that work appear in the delegated category.

Please consider stating expressly that the most specific category controls and providing a decision table with examples of full committee review, delegated review, registration, exemption, and NIH review. This would support consistent decisions across institutions.

b. Provide streamlined pathways for routine minimal-risk activities

We encourage NIH to consider exemptions or administrative registration for activities that a documented institutional screening process determines present minimal biosafety risk. Examples include commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms.

Allowing these pathways, with institutional discretion to elevate review when local circumstances warrant, would help preserve IBC capacity for higher-risk activities while retaining appropriate institutional oversight.

3. Risk Assessment and the Continued Utility of Risk Groups

a. Distinguish genetic engineering from other forms of change

We appreciate the intent to account for changes that may affect an organism's risk. The proposed definition of genetic modification includes passaging, reassortment, and chemical or radiological means, which could also bring conventional selection, adaptation, mutagenesis, and routine RG1 work into mandatory review without a demonstrated increase in biosafety risk.

We ask NIH to distinguish deliberate genetic engineering from these other processes and calibrate oversight to the resulting phenotype and risk. Examples would help institutions determine when an activity changes the level of oversight required.

b. Support consistent risk assessment and containment decisions

We support the emphasis on risk assessment and mitigation. Institutions would benefit from practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk.

We also encourage NIH to retain a clear distinction between Risk Group (RG), which describes agent characteristics, and Biosafety Level (BSL) and Animal Biosafety Level (ABSL), which describe containment. Guidance explaining how these classifications inform, but do not substitute for, activity-specific risk assessment would be valuable.

4. Roles, Responsibilities, Compliance, and Transparency

a. Establish a clear foundation for IBC authority and independence

We support the requirement for an IBC and encourage NIH to pair its responsibilities with explicit institutional authority, support, and independent decision-making. An "Establishing an IBC" subsection could provide a consistent foundation while allowing flexibility in institutional structure. We offer the following language for consideration:

> The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.
>
> As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

b. Distinguish substantive oversight from administrative support

Clearer separation of IBC oversight functions, committee procedures, and administrative tasks would help institutions assign work appropriately and support timely responses. Please consider specifying that the IBC's substantive responsibilities include:

- Reviewing the biosafety program, including practices, training, emergency preparedness, and continued compliance.
- Conducting or directing periodic, risk-based evaluations of facilities, equipment, and containment, with findings, deficiencies, and reasonable corrective plans and schedules reported to the Institutional Official or designee.

- Reviewing concerns, incidents, unsafe conditions, and noncompliance; requiring corrective measures; overseeing resolution; and recommending improvements to facilities, training, and resources.
- Approving, requiring modifications to secure approval, or withholding approval of covered activities and significant changes before implementation.
- Suspending or withdrawing approval and requiring cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

We also encourage flexibility for qualified staff to conduct evaluations under written institutional procedures, with intervals proportionate to risk and IBC responsibility retained for oversight determinations. The IBC would approve its minutes and substantive determinations, while staff could prepare, retain, redact, and post records; communicate decisions; track deadlines; and prepare authorized submissions.

Please also clarify immediate stop-work authority and subsequent IBC review. Qualified response teams need to be able to investigate and take immediate protective action without waiting for a committee meeting.

c. Align accountability with authority

The expanded responsibilities assigned to BSOs and IBCs would be more effective if accompanied by explicit access to facilities and relevant records, direct reporting and escalation pathways, and authority to require corrective measures and stop or suspend unsafe work when necessary. We ask NIH to make these authorities clear so that institutional personnel can fulfill the responsibilities the policy assigns to them.

d. Support experienced program leadership

We appreciate the draft's recognition of the Biological Safety Officer's role. Where BSO duties are assigned to another official, equivalent qualifications and institutional support remain essential.

Please consider requiring each covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to its research portfolio. Expectations for qualifications, institutional access, reporting relationships, resources, and escalation of unresolved risks would help institutions establish effective leadership. An official performing BSO duties would need equivalent qualifications for those duties.

Guidance on the relationships among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official would also be helpful. In particular, institutions would benefit from clarification of which roles may be combined, how independence is protected, and whether the BSO's IBC role includes program administration in addition to voting membership. We encourage NIH to emphasize experience and functional authority, comparable to other institutional oversight leaders such as animal welfare directors or institutional veterinarians, while allowing flexibility in titles and administrative placement.

e. Clarify occupational health and safety expectations

We welcome the recognition of occupational health and safety as part of an effective biosafety program. The draft notes that other regulations and policies may require an Occupational Health and Safety Program. Clear triggers, assigned authorities, and responsibility for developing and communicating required procedures would help institutions understand and coordinate these obligations.

f. Clarify committee governance

Additional guidance on quorum and voting would support consistent committee decisions. We ask NIH to specify that a member recused because of a conflict does not count toward the quorum for that matter and to explain the voting denominator after recusal.

Institutions would also welcome expectations for remote participation, use of ad hoc consultants, and reasonable approaches for institutions that have difficulty recruiting unaffiliated members.

g. Map retention requirements to record types

A record-retention table would be a practical aid to implementation. Please consider including protocols, risk assessments, delegated reviews, training, assurances, meeting minutes, incident reports, and records spanning multiple awards. Identifying the triggering event, retention period, public availability period, responsible custodian, and any superseding award or legal requirements would reduce uncertainty and inconsistent practice.

h. Provide a predictable Biosafety Assurance process

We appreciate the value of an institutional Biosafety Assurance and ask NIH to provide a standardized template and a predictable submission, approval, and renewal process. These resources would promote consistent submissions and help prevent interruptions during timely renewal.

A template could distinguish required, conditional, and optional fields and address institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. We encourage NIH to retain substantive obligations in the policy itself rather than introduce additional requirements through templates.

Please also specify required institutional signatures, the submission system, completeness criteria, and how timely renewals will be handled while NIH review is pending. Clarifying which information must be public and which may be submitted directly to NIH when public posting is inappropriate or unavailable would further support implementation.

5. Incident Reporting and Safety Learning

a. Preserve local management of lower-risk events

We support reporting that enables NIH to identify significant risks and strengthen biosafety. Please consider preserving local IBC management of lower-risk events and near misses, without requiring public posting of every internally reviewed minor event or unredacted identifying information. A

proportionate approach would support prompt reporting and corrective action while focusing federal reporting on events that warrant that level of oversight.

b. Use aggregate reporting to advance transparency and learning

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For a voluntary learning system to be effective, institutions and researchers need to understand its confidentiality protections, disclosure boundaries, and relationship to enforcement. Clear parameters would help build confidence in participation and improve the usefulness of the information collected.

c. Explain how investigator duties and reporting pathways interact

Section III-C assigns investigators safe-research responsibilities that intersect with institutionally managed facilities and services. We would welcome clarification of how these responsibilities are shared so investigators understand which actions they must take directly and which require institutional coordination.

Please also explain how confidential voluntary reporting to NBDSAC interacts with mandatory NIH reporting and public posting. Clear limits on confidentiality and a clear distinction between voluntary learning submissions and required reports would help institutions participate with an accurate understanding of their obligations.

6. Implementation Resources and Timeline

a. Provide practical implementation resources

We appreciate NIH's efforts to support institutions through this transition. The following resources would be particularly valuable before implementation begins:

- A Biosafety Assurance template and model institutional policies.
- Decision trees, risk-assessment forms, and worked examples.
- Training materials for IBC members, BSOs, PIs, and staff.
- Sample completed minutes and incident reports, with clear redaction guidance.
- A national Risk Group and containment determination database.
- Guidance for external, shared, and consortium IBC models.

Making these resources available with the final policy would help institutions develop consistent procedures and avoid repeated revisions as expectations become clearer.

b. Allow sufficient time for a coordinated transition

Implementing the proposed policy will require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research. We respectfully request at least 12 months for full implementation after final guidance and required templates are available.

Please consider staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, allowing conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work, would help institutions manage the transition effectively. Preserving staggered renewal cycles would also reduce avoidable backlogs.

Thank you for considering these recommendations and for inviting institutional input throughout the policy's development. UM supports NIH's biosafety goals and welcomes continued engagement to help develop a final policy that strengthens safety, supports consistent oversight, and can be implemented effectively across institutions with varied research portfolios and resources.

441. Leyma De Haro

I am responding: On behalf of myself

Name: Leyma De Haro

Name of Organization:

Type of Organization: Other

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH_Biosafety_Policy_Summary_Comments.docx

Summary of Comments on the Draft NIH Biosafety Policy

NIH Notice NOT-OD-26-112 | Draft policy for research involving biohazards | October 19, 2026

Purpose. This working summary identifies recommendations for strengthening the proposed policy with respect to emerging biotechnology, institutional oversight, and practical implementation. These are proposed comments, not requirements already established by NIH.

1. Address mirror life explicitly

Priority: High | Relevant draft sections: Sections II, IV-1, V-A, V-C

Clarify whether wholly or partially mirror-image biological systems fall within the definition of a biohazard or novel organism. Distinguish useful research on nonreplicating mirror-image molecules from work toward self-replicating mirror organisms. Provide a precautionary referral and assessment pathway for the latter, addressing uncertainty about biological interactions, environmental persistence, detection, and effective containment. Avoid assigning conventional Risk Groups without adequate evidence.

2. Modernize assessment of AI-designed and de novo biological systems

Priority: High | Relevant draft sections: Sections II, V-B, V-C

Explicitly address AI-designed proteins, genetic circuits, and organisms with no meaningful parental organism. Supplement sequence provenance and parental Risk Group considerations with functional, phenotype-based, context-dependent, and uncertainty-aware assessment. Treat lack of an identified hazardous parent as insufficient evidence of safety.

3. Define oversight for autonomous and AI-directed experiments

Priority: High | Relevant draft sections: Sections III-B, III-C, V-D, V-E

Specify how IBC-approved research applies when an automated or AI-driven system changes experimental parameters or selects subsequent experiments. Encourage defined, validated operating envelopes, pre-established escalation triggers, audit trails, safeguards against out-of-scope operations, and human authority to intervene. Require renewed review when changes materially alter risk.

4. Enable validated AI-assisted biosafety risk assessment

Priority: High | Relevant draft sections: Sections III-B, III-C, V

Recognize computational decision-support tools for literature synthesis, protocol triage, identification of missing hazard information, and documentation. Make clear that IBCs and investigators retain decision authority. Provide guidance on tool validation, evidence traceability, accuracy, uncertainty, confidentiality, and periodic reevaluation.

5. Build the National Biosafety Data and Safety Analysis Center as a scientific resource

Priority: High | Relevant draft sections: Sections II, III-C, III-D

Support the proposed center and develop standardized, interoperable incident and near-miss data fields, including exposure context, causal factors, process and equipment conditions, and corrective actions. Enable rigorous trend analysis while protecting confidentiality and guarding against re-identification. Account for reporting-culture differences before making comparisons among institutions.

6. Integrate cyberbiosecurity where digital compromise creates biological risk

Priority: High | Relevant draft sections: Sections III-A, III-B, V-D, V-E

Include proportionate evaluation of connected instruments, automated systems, electronic protocols, biological inventories, laboratory information systems, and facility controls. Clarify coordination with institutional cybersecurity teams, and when a digital incident that affects containment or safe experimental operation warrants biosafety investigation or reporting.

7. Clarify boundaries of biosafety, biosecurity, and dual-use oversight

Priority: Medium | Relevant draft sections: Sections II, III-B, IV

Explain referral and coordination mechanisms among IBCs, institutional research security functions, and applicable federal oversight frameworks. Do not imply that IBCs alone should adjudicate all dual-use or information-security issues. Avoid duplicate reviews and conflicting determinations.

8. Strengthen institutional implementation and proportional oversight

Priority: Medium | Relevant draft sections: Sections II, III-A, III-B, IV

Provide actionable criteria for delegated review and for determining when a protocol change requires reassessment. Evaluate the net workload associated with expanded coverage, Biosafety Assurances, three-year de novo reviews, incident reporting, and public posting. Supply standardized templates, training, transition support, and realistic workload assumptions.

9. Balance transparency with protection of sensitive information

Priority: Medium | Relevant draft sections: Sections III-A, III-B

Clarify redaction criteria for IBC minutes and incident reports. Protect confidential research details, individual privacy, physical security vulnerabilities, and sensitive operational information while ensuring meaningful public accountability. Provide consistent examples and a process for resolving disclosure disagreements.

10. Clarify environmental and nonhuman risk boundaries

Priority: Medium | Relevant draft sections: Sections II, V-A, V-B, V-E

Resolve the tension between a scope centered on human health and risk assessments that also consider ecological and nonhuman impacts. Explain handling of gene-drive systems and other novel synthetic organisms for which environmental effects may be central, including where field-release activities fall outside this laboratory-focused policy.

Overall recommendation

Retain the proposed expansion from recombinant-DNA-focused guidance to risk-based oversight of biohazards. Strengthen it with forward-looking provisions for novel biological architectures, AI-enabled design and experimentation, and digitally connected laboratories. Pair these provisions with scientifically grounded, proportionate review procedures and a national learning system for biosafety incidents and near misses.

Primary sources

NIH, Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards, NOT-OD-26-112 (August 19, 2026). https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

NIH Office of Science Policy, public comment form: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

Submission note: NIH lists October 19, 2026 as the response deadline and advises against including information that should not be made public.

442. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Public Posting Requirements Create Significant Administrative Burden

Observation
The proposed transparency requirements represent a substantial expansion of public disclosure obligations compared with the historical framework.
Transparency is important and can strengthen public trust. However, the operational burden associated with public posting requirements should not be underestimated.

Real-World Implementation Impact
Public posting involves far more than publishing documents online.
Before posting materials, institutions may need to:
• Conduct privacy reviews;
• Conduct security reviews;
• Redact sensitive information;
• Review employment and student information;
• Evaluate proprietary research information;
• Address legal considerations;
• Maintain public websites; and
• Retain records over time.

For biosafety programs with limited staffing, these responsibilities will often be managed by the same individuals responsible for:
• Protocol review;
• Laboratory inspections;
• Risk assessments;
• Incident response; and

• Investigator support.
Every hour devoted to preparing public-facing documents is an hour unavailable for direct biosafety activities. For example, in my professional capacity, I will devote a minimum of eight work hours to preparing meeting minutes that are publicly available.

Why This Matters
The question is not whether transparency is valuable.
The question is whether implementation requirements are calibrated in a way that allows institutions to achieve transparency objectives without weakening operational biosafety functions.
Particularly at smaller institutions, additional administrative obligations may disproportionately affect available biosafety resources.

Recommendation
NIH should:
1. Develop written redaction guidance, not simply such as examples.
2. Create model posting procedures.
3. Clarify confidentiality expectations.
These measures would support transparency while reducing implementation burden.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

443. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed guidelines as currently written will bring research to a halt! The proposed scope is unattainable for any decently sized research institution. The request to review and renew the current NIH Guidelines was to use the expertise of the biosafety professionals in the field that oversee use of organisms in the lab. The ask was to remove oversight over organisms that are not considered a risk. The proposal increases the oversight by volumes without any increased safety or security to our researchers!

Can a blanket registration be submitted per institution for material where the risk level doesn't change, regardless of modification?

What is the benefit to registering all transgenic mice. The request during the listening sessions was to stop having to register lower risk organisms that cannot have an effect on environment or cause human disease. Instead of exempting drosophila, you now have added millions of transgenic mouse strains. What is the risk of these transgenic mice? How does one even do a risk assessment from one transgenic mouse to another, when they are all housed at ABSL-1? Will NIH provide training and guidance to BSOs on how to perform a comprehensive risk assessment on transgenic mice? I've been doing this for 16 years and won't know where to start!

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: For downgrades for RG3 and RG4 organisms to lower levels: Can other institutions use these approved downgrades that were issued to a single institution? What about downgrades that the local IBC approved in the past, will those be grandfathered in or do such requests now need to be resubmitted to NIH for approval?

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposal states that records must be retained 3 years past the submission of an award's final financial report. The

problem with this is that the minutes tied to this submission will also have to retained past the 5 years that they are posted on an institution's website. The administrative burden to link, find, and maintain all the minutes tied to a grant (or often multiple grants) will be huge. What happens when the PI leaves the institution, but the grant still exists, just with another institution? Does the previous institution need to continue to retain those records?

6. Other feedback relevant to this resource: Escalation of biosafety oversight without any additional funding or support will be unfeasible to attain. Implementing this proposed policy as written will be a huge burden on biosafety professionals, and will decrease the time they have available to perform vital biosafety assessments that are not captured in this policy. The addition of an overwhelming amount of oversight on material that is either low risk or, like in human cells, the risk doesn't change from one version to another, just has no added value to biosafety. Additionally, the proposed policy is poorly written, with many of the items mentioned not clearly defined or not defined at all, as in the case of DGMO.

444. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Incident Reporting Requirements Should Be Harmonized With Existing Federal Reporting Systems

Observation
The draft introduces new incident-reporting requirements that may overlap with existing federal reporting obligations.
Many research institutions already report certain incidents through established pathways involving other federal agencies.

Real-World Implementation Impact
When a laboratory incident occurs, biosafety personnel must immediately focus on:
• Exposure assessment;
• Medical evaluation;
• Laboratory containment;
• Corrective actions;
• Follow-up investigations;
• Stakeholder communications; and
• Regulatory notifications.
In a recent incident response in which I participated, biosafety personnel spent several days coordinating

exposures assessments, communications, corrective actions, and follow-up activities.

Additional reporting obligations may require personnel to prepare multiple reports containing substantially similar information for different recipients.
This effort occurs during the same period when immediate response activities are most critical.

Why This Matters
Duplicative reporting may increase administrative burden without improving safety outcomes.
It can also create opportunities for inconsistencies if multiple reports are prepared independently for different agencies.
Resources dedicated to repetitive reporting are resources unavailable for incident mitigation and prevention activities.

Recommendation
NIH should:
1. Harmonize reporting requirements with existing federal programs (one example is the FSAP Form 3 reporting process).
2. Accept equivalent reports where appropriate.
3. Develop cross-reporting mechanisms.
4. Eliminate duplicative information requests.
5. Clarify how public posting requirements interact with existing reporting frameworks.
The most effective incident-reporting systems maximize learning and accountability at the institutional level while minimizing unnecessary duplication.

445. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Federal vs. Local Oversight for Emerging, Novel, and Unclassified Agents

Observation
The draft requires NIH involvement for certain emerging, novel, or unclassified agents while also emphasizing institutional risk assessment.

Real-World Implementation Impact
In practice, IBCs and biosafety professionals will frequently encounter agents for which no explicit BMBL containment recommendation exists. Many institutions may feel obligated to seek NIH review out of caution, even for agents that are routinely handled safely under existing frameworks.

Why This Matters
The absence of clear thresholds may increase requests for federal review, create delays, and reduce the efficiency of local risk assessment processes.

Recommendation
NIH should provide objective criteria, examples, and decision trees identifying when local review is sufficient and when federal review is required.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

446. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Renewal and De Novo Review Pathways Require Clarification

Observation
The draft does not clearly explain how de novo renewals interact with delegated review pathways.

Real-World Implementation Impact
Protocols that initially qualified for delegated review may be routed to full committee review solely because they are undergoing renewal.

Why This Matters
The review pathway should be driven by risk rather than administrative timing.

Recommendation
NIH should clarify whether renewals follow the same review pathway as the underlying activity.

447. Joanie Ryan

I am responding: On behalf of myself

Name: Joanie Ryan

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy scope needs to be clarified to ensure it applies consistently across all research settings involving biological hazards, not just laboratory environments. As written, the scope may be interpreted as excluding activities conducted in animal facilities, greenhouses, agricultural settings, field studies, and other nonlaboratory environments where biological hazards are present.

The definition of covered biohazards should also extend beyond agents that cause disease in humans. Biological agents may present meaningful risks to human, animal, plant, or environmental health without causing human disease. Coverage should be based on risk rather than human pathogenicity alone.

In addition, exclusion of plants may create oversight gaps. Clarification is needed regarding how genetically modified plants, plant pathogens, plant-associated toxins, agricultural pests, and related organisms will be addressed. A comprehensive biosafety framework should reflect a One Health approach that considers human, animal, plant, and environmental health impacts.

Several definitions also require additional clarification to reduce subjective interpretation and promote consistent implementation. For example, it is unclear whether the term "toxins" refers only to biological toxins or to all toxic substances, and whether "prions" includes prion diseases affecting nonhuman species. A glossary or cross-reference to established definitions would improve consistency and reduce ambiguity across institutions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The ideal risk-based oversight framework reserves federal reporting and review requirements for activities presenting the greatest potential risk while allowing institutions flexibility to manage lower-risk activities locally.

Additional clarification is needed regarding the distinction between reportable incidents, compliance

violations, and events that can be managed through institutional corrective action processes. A tiered approach to incident reporting would help focus federal oversight on significant events while reducing administrative burden associated with minor incidents that do not involve exposure, environmental release, or increased risk.

The policy should also clarify whether all protocol renewals require the same level of review or whether continuing review requirements can be commensurate with risk and program changes.

3. Continued utility of Risk Groups: Risk Groups continue to provide useful baseline information regarding the intrinsic hazards associated with biological agents and remain valuable as an initial component of risk assessment. They provide a common language from which to start.

However, Risk Groups alone do not adequately address risks associated with genetically modified organisms, novel constructs, altered host range, modified virulence, toxin production, or other engineered characteristics. Institutional risk assessments should continue to consider both the agent and the specific experimental manipulations being performed.

Additional guidance is needed regarding how institutions should determine risk groups under the proposed framework, particularly because the draft does not appear to identify whether information currently provided in Appendix B of the NIH Guidelines will continue to be maintained. BMBL does not include risk groups, and in some cases provides a BSL range. Clear guidance regarding the relationship between Risk Groups, project-specific risk assessment, and Biosafety Levels would improve consistency across institutions.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Many institutions already apply biosafety principles to activities beyond those explicitly required by regulation or funding conditions. NIH can encourage broader adoption by providing practical tools, templates, decision trees, training resources, and examples that can be implemented regardless of funding source.

The policy should emphasize education, technical assistance, and model practices rather than creating the perception that voluntary adoption may result in additional reporting obligations or enforcement consequences. Institutions are more likely to voluntarily align with NIH expectations when resources are clear, accessible, and scalable to programs of varying sizes.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The incident reporting template would benefit from clearer reporting thresholds and definitions. Additional guidance is needed regarding whether incidents such as spills contained within primary containment, minor events without exposure or release, or needlesticks involving sterile needles require reporting at each BSL (eg sterile needlestick BSL-3).

Clarification is also needed regarding:

Whether "within 24 hours" refers to calendar hours or business hours;
Whether the incident reporting template is required for events that are not NIH-reportable;
How submitted incident information may be used in compliance, enforcement, or funding decisions.

The meeting-minutes template appears to require documentation that many institutions already maintain in separate records, including risk assessments, training documentation, inspections, occupational health records, and compliance activities. Requiring this information to be duplicated in meeting minutes significantly increases administrative burden without improving oversight. Institutions should be permitted to reference existing records whenever appropriate.

Additionally, public posting of incident reports with the proposed information included will discourage reporting and undermine safety culture if personnel become concerned about privacy, reputational impacts, litigation risk, or other unintended consequences. Careful consideration should be given to de-identification standards, redaction requirements, aggregation of minor events, and protections for security-sensitive information.

6. Other feedback relevant to this resource: The proposed implementation timeline will be challenging for institutions that must revise policies, train personnel, submit assurances, and review existing research activities. A phased implementation process would facilitate compliance while minimizing disruption to ongoing research.

Additional guidance would be beneficial in the following areas:

Definitions of key terms, including incident, compliance violation, failure to maintain IBC approval, toxin, and prion.
Determination of Risk Groups and Biosafety Levels under the new policy framework.
Expectations for protocol renewals and continuing review.
Incident-reporting thresholds and examples of reportable versus non-reportable events.
NIH review timelines for Biosafety Assurances, containment determinations, requests to lower containment levels, and incident reviews.
Transitional or provisional mechanisms for institutions awaiting NIH review.

A consolidated glossary of policy terms and decision-making examples would improve consistency of implementation and reduce variability in interpretation across institutions. Published response-time expectations and status-tracking processes would also help institutions plan and prioritize submissions while maintaining ongoing research operations.

448. Jonathan A Javitch

I am responding: On behalf of myself

Name: Jonathan A Javitch

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): molecular pharmacology / neuroscience

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached. 'Potential risk to human health' is undefined, so scope will vary by IBC. I ask NIH to define it, or list presumptively exempt activities, and carry forward the Guidelines' Section III-F / Appendix C exemptions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached. The delegated-review vector tier should turn on replication competence and transgene hazard, not integration. 'Low risk transgene' needs a definition. Clarify whether a capsid swap requires re-review, what a registration covers, and the expected turnaround.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached. Public posting of IBC minutes and 24-hour incident reporting should be piloted at a subset of institutions first. Define what starts the 24-hour clock.

6. Other feedback relevant to this resource: N/A

Uploaded File: comment-NOT-OD-26-112-v2.docx

Description: Overall assessment of the proposal and related issues.

Public Comment on the Draft NIH Biosafety Policy for Research Involving Biohazards
Notice NOT-OD-26-112 · Federal Register, September 14, 2026

I am a neuroscientist at Columbia University, where I direct the Division of Preclinical Research at the New York State Psychiatric Institute. My laboratory studies the molecular mechanisms of G protein-coupled receptors, including dopamine, opioid, and metabotropic glutamate receptors, from purified protein through cultured cells to behaving mice. We routinely express receptors in cultured cell lines, express proteins in *E. coli* and yeast, deliver constructs with adeno-associated viral vectors into mouse brain, use bacterial toxins that are not Select Agents, and maintain multiple transgenic mouse lines at ABSL-1. Under the current NIH Guidelines, nearly all of that work is either exempt or requires only notice to our IBC at the time it begins.

I am not writing to argue against biosafety oversight. The Guidelines are organized around recombinant nucleic acids, so work with wild-type pathogens and with toxins falls outside them, and bringing that work under a single policy is reasonable.

I am writing because the draft, read as written, brings a large body of work that poses no credible risk to human health under committee review, and because the terms meant to limit its reach are left undefined or poorly defined, which will lead to differences in interpretation and inconsistent application.

The Policy's scope turns on a phrase that is not defined

The draft defines genetic modification to include introducing into cells, organisms, or viruses nucleic acid that "can be transcribed or translated." Transfecting HEK293 cells with a receptor cDNA, expressing a receptor fragment in *E. coli*, and making a reporter strain in yeast all meet that definition.

What keeps that definition from reaching the whole of molecular biology is its qualifier: research involving biohazards is research carrying "known or potential risk to human health." Reviewing work that carries real risk to human health is reasonable, and I am not arguing otherwise. The difficulty is that "potential risk" is nowhere defined, and the activities I have listed carry no meaningful risk at all.

Each IBC will therefore draw the line somewhere of its own, and identical experiments will be exempt at one institution and registered at another.

The Guidelines drew that line explicitly. Section III-F and Appendix C exempt the *E. coli* K-12 and *S. cerevisiae* host-vector systems, tissue-culture work with characterized cell lines, and the breeding of transgenic rodents at BSL-1. The draft has no counterpart to any of them, and delegated review is not an exemption: work in that tier still requires a registration, an amendment when the work changes, and de novo review every three years.

I urge NIH to define "potential risk to human health," or to publish a list of activities presumptively outside the Policy, and to carry explicit exclusions into the final policy for the activities now exempt under Section III-F and Appendix C.

The vector tier is drawn on integration, which is not strictly where the risk is

Delegated review covers "replication incompetent, nonintegrating viral vectors expressing reporter or low risk transgenes."

Integration is an inadequate proxy for hazard. A replication-incompetent vector that integrates and carries a fluorescent sensor is less hazardous than many non-integrating vectors carrying biologically active genes. Third-generation lentiviral vectors are replication-incompetent, are handled at BSL-2, and are in routine use across neuroscience, but because they integrate, this wording puts them outside the delegated tier and into full committee review.

"Low risk transgene" is also undefined.

We screen AAV serotypes for tropism, and the draft does not say whether substituting a capsid, with no change to the transgene, requires new review.

I urge NIH to define the tier by replication competence together with transgene hazard, to define "low risk transgene," and to state whether serotype or capsid substitution alone triggers re-review.

The draft does not say what a registration covers

The draft requires that "any changes to the approved research that have the potential impact on the original biosafety assessment must be reviewed and approved by the IBC, or its delegate, before such research is conducted." It does not say whether a registration is per project, per agent, or per award, and it gives no examples of changes that meet that threshold.

A single project in my laboratory may use one viral vector, one bacterial toxin, and multiple mouse lines. Each element is individually low risk and individually delegable. Whether that project is one registration or several, and whether adding a line or a construct requires approval before the work starts, determines whether the project is registered once or returns to the committee each time it changes.

The Policy bars any covered research before IBC approval. Work that today requires only notice to the IBC when it begins, under Section III-E, and work that is exempt under Appendix C would both move behind prior approval, so experimental timing would depend on committee turnaround. The draft sets no turnaround requirement for delegated review; a delegated approval need only be reported to the IBC at its next scheduled meeting.

I urge NIH to state what a registration covers, to give examples of changes that require re-review, and to set an expected turnaround for delegated review.

Public posting and 24-hour reporting are substantial obligations that have not been tested

The draft would have institutions post approved IBC minutes and all incident reports on a public webpage, and notify NIH within 24 hours of learning of an incident posing significant risk to human health.

The draft does not say what starts the 24-hour clock. The facts of an incident are often unclear for the first day or two.

Minutes are useful to a committee because members say plainly what they think might go wrong. Minutes written for publication are written differently.

I urge NIH to assess both requirements at a subset of institutions before applying them everywhere.

I ask NIH to define the terms that set the Policy's scope, and to carry the existing exemptions forward.

Thank you for considering these comments.

Jonathan A. Javitch, M.D., Ph.D.
Lieber Professor of Experimental Therapeutics in Psychiatry
Professor of Molecular Pharmacology and Therapeutics
Columbia University

449. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy goes beyond the initial scope of the policy listed in Section I of the proposal. There is little clarity on what exactly should be included in the registrations or not. Oddly enough, recombinant plant material is now excluded, though risk of release of recombinant plant could be detrimental to US agriculture.
What are recombinant plants being removed from the oversight of this policy? While this material may not be hazardous to humans directly but could very well affect local and global agriculture. Is it enough to capture recombinant plants under USDA permits where biosafety professionals do not have access to applications or knowledge of what researchers are working with?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Why can't an existing registration be renewed after 3 years? What is the purpose of requiring a de novo registration? Currently my institution uses online platform where renewing an existing registration will copy it to a new entry with a new IBC number. Is a straight copy of an existing registration acceptable when generating a "de novo" renewal?

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The notification of a potential LAI is unattainable. If an institution works with influenza and staff at that institution get sick with flu, does the institution have to test if it's the same strain. Do all flu cases at an institution have to be reported? Or only from staff in the lab setting? This would also force all staff to self-report. Many people may get sick with a common cold and just stay home and not see a doctor or report anything, knowing it will pass in a few days.

6. Other feedback relevant to this resource: Is material that has been in ownership at an institution grandfathered in? Do institutions that have not had to register material, but now included in the policy,

need to go back and register such past material already in ownership or only newly acquired material that now falls under the policy?

450. American Society of Gene and Cell Therapy (ASGCT)

I am responding: On behalf of an organization

Name: Caitlin McCombs

Name of Organization: American Society of Gene and Cell Therapy (ASGCT)

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Nonprofit Government Relations

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Cell and Gene Therapy

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: ASGCT encourages NIH to clarify the proposed definition of "genetic modification" to ensure it accurately reflects the range of technologies and research activities covered by the policy. As currently written, the definition includes the introduction of nucleic acids that "can be transcribed or translated," without clearly distinguishing between technologies that permanently alter the genome and those that do not.

This broad language could create confusion regarding the classification of certain technologies, including mRNA-based products, non-integrating gene therapies, and other approaches that introduce genetic material without permanently modifying a recipient's genome. While these technologies that do not modify the genome may warrant appropriate biosafety oversight, the terminology used to describe them should accurately reflect their biological characteristics and intended applications.

ASGCT urges NIH to refine this definition or provide accompanying clarification that distinguishes between the introduction or expression of genetic material, and permanent changes to the genome. Such clarification would help ensure consistent interpretation of the policy while avoiding confusion among researchers, policymakers, and the public. Clear, scientifically grounded terminology is particularly important to maintain public understanding and confidence in emerging biomedical technologies.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Allowing certain activities to undergo delegated Institutional Biosafety Committee (IBC) review could reduce unnecessary administrative burden while maintaining appropriate safety protections. As NIH considers this approach, ASGCT encourages the Institutes to ensure that oversight requirements reflect the actual risks of individual technologies and research activities. CGT research encompasses a broad range of approaches, including viral vectors, genetically modified cells, and other emerging platforms with distinct characteristics and safety profiles. , Oversight requirements should account for established scientific evidence, prior safety data, and modifications specifically designed to reduce risk, ensuring that the level

of review is proportional to the risks of the research – rather than determined solely by broad technology classifications.

ASGCT also encourages NIH to clarify how the proposed oversight framework would interact with existing institutional and FDA requirements for CGT clinical research. Clear expectations and coordination across oversight bodies will be important to avoid unnecessary duplication or delays while maintaining rigorous safety standards.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): ASGCT recognizes the importance of institutional accountability and appropriate enforcement mechanisms to maintain strong biosafety standards. However, the proposed policy's broad scope, coupled with provisions allowing noncompliance to affect current and future NIH funding, raises concerns about the potential consequences of unclear or inconsistently interpreted requirements.

The proposal states that institutions receiving NIH funding must ensure compliance for research conducted or sponsored by the institution, regardless of the individual research project's funding source. It further provides that noncompliance may result in additional funding conditions, termination of awards, or impacts on future funding decisions. Biomedical research programs often require years of continuous effort before meaningful outcomes can be achieved. Long-term preclinical studies, specialized manufacturing facilities, multi-year clinical trials, longitudinal patient follow-up, and complex public-private partnerships cannot be paused and restarted without serious impact on patient participants and institutions. For CGTs, where a single program may span a decade from IND filing to BLA approval, , mid-stream terminations do not merely delay results. They can end programs entirely. Although similar institutional compliance obligations and funding-related enforcement mechanisms exist under the current Guidelines, the expanded scope of the proposed policy, coupled with the longer development timelines associated with CGTs, makes it especially important that institutions have a clear understanding of their responsibilities.

Without sufficient detail regarding how the new requirements will be interpreted and enforced, researchers and institutions may face uncertainty about whether established practices remain compliant. This uncertainty could discourage research activities, create unnecessary administrative burden, or disrupt ongoing projects, even where there is no meaningful change in biosafety risk. Nearly every FDA-approved CGT available to patients today traces its origins to decades of federally supported scientific research. Maintaining consistency and predictability in federal research funding is essential to sustain the basic research that has helped produce today’s pipeline of more than 4,400 therapies.

ASGCT therefore encourages NIH to establish clear, consistent, and transparent compliance standards before implementing any new policy. Enforcement should be proportional to the nature and severity of a violation, with appropriate opportunities for institutions to identify and correct deficiencies. An explicit appeals process would help mitigate some of the uncertainty around the policy’s implementation. Given that the detailed examples and guidance in the current Guidelines would be removed, NIH should ensure that any appeals process is clearly defined and fully transparent. NIH should also clarify how compliance

concerns involving individual research activities would be evaluated and ensure enforcement actions do not unnecessarily jeopardize unrelated programs or funding under an institution's broader research portfolio.

These safeguards would help ensure that biosafety oversight remains focused on protecting researchers and the public while providing institutions with the predictability needed to plan and conduct biomedical research.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: ASGCT is concerned that the proposed policy substantially reduces the level of detail contained in the Guidelines. Currently, there are extensive examples, definitions, and specific requirements that researchers and institutions have relied upon to determine appropriate biosafety practices. While a more streamlined policy may offer some benefit, removing this detail without providing comparable guidance could create uncertainty regarding how established research activities will be evaluated under the new framework.

For CGT researchers, this uncertainty may be particularly consequential given the diversity of technologies and research approaches used across the field. ASGCT encourages NIH to retain or replace the practical examples and technical guidance provided under the existing Guidelines, including clear explanations of how the new requirements apply to research already being conducted. Broad or opaque application of the new guidelines may discourage institutions from undertaking ambitious, high-investment projects. It could make it harder to attract partnerships that translate federal discoveries into domestic manufacturing. The more limited detail in this new policy could be particularly damaging to emerging investigators and early-career scientists, who may require more guidance on emerging technologies and best practices. In particular, NIH should issue implementation resources that clarify whether and how established research practices will be affected by the transition to the new policy.

Finally, ASGCT reemphasizes the importance of providing sufficient implementation guidance before the new policy takes effect. We encourage NIH to make these materials available for public review before finalizing or implementing the policy, particularly where they will determine how existing research practices are classified and overseen. Detailed examples, frequently asked questions, and guidance addressing common CGT research activities would help institutions prepare for the transition. NIH should also consider whether the proposed six-month implementation period provides sufficient time for institutions to evaluate existing research, update procedures, and ensure compliance without interrupting ongoing studies.

Uploaded File: Biosafety-RFI-Final-draft.docx

Description: Please see attached for comments from the American Society of Gene and Cell Therapy (ASGCT).

American Society of Gene + Cell Therapy

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October 19, 2026

Office of Science Policy
National Institutes of Health
6705 Rockledge Dr #750
Bethesda, MD 20817

Re: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Sir/Madam,

The American Society of Gene & Cell Therapy (ASGCT) appreciates the opportunity to provide comments on the National Institutes of Health's (NIH) *Draft Biosafety Policy for Research Involving Biohazards* (NOT-OD-26-112).

ASGCT is a nonprofit professional membership organization comprised of more than 7,300 scientists, physicians, patient advocates, and other professionals working on cell and gene therapies (CGTs) in settings such as universities, hospitals, and biotechnology companies. The mission of ASGCT is to advance knowledge, awareness, and education that leads to the discovery and clinical application of genetic and cellular therapies to alleviate human disease.

ASGCT acknowledges NIH's stated objectives to modernize biosafety oversight, strengthen research safety, and establish requirements that reflect the evolving biomedical research landscape. We recognize the value of a risk-based oversight framework that maintains appropriate safeguards while reducing unnecessary administrative burden for lower-risk research. However, as NIH considers replacing its longstanding *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ("Guidelines"),[1] ASGCT encourages the agency to provide greater clarity regarding the scope and application of the proposed policy, particularly for established research practices and emerging CGT technologies covered by the Guidelines.

Our comments focus on the need for clear, scientifically grounded definitions, consistent compliance expectations, and sufficient implementation guidance to ensure that the new framework supports safe research without introducing unnecessary uncertainty or disruptions to ongoing scientific work.

We offer the following comments regarding the new proposed policy, should replacement Guidelines be finalized:

[1] National Institutes of Health, Office of Science Policy (2024 April). *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

1. **Scope of research covered by the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.**

ASGCT encourages NIH to clarify the proposed definition of "genetic modification" to ensure it accurately reflects the range of technologies and research activities covered by the policy. As currently written, the definition includes the introduction of nucleic acids that "can be transcribed or translated,"[2] without clearly distinguishing between technologies that permanently alter the genome and those that do not.

This broad language could create confusion regarding the classification of certain technologies, including mRNA-based products, non-integrating gene therapies, and other approaches that introduce genetic material without permanently modifying a recipient's genome. While these technologies that do not modify the genome may warrant appropriate biosafety oversight, the terminology used to describe them should accurately reflect their biological characteristics and intended applications.

ASGCT urges NIH to refine this definition or provide accompanying clarification that distinguishes between the introduction or expression of genetic material, and permanent changes to the genome. Such clarification would help ensure consistent interpretation of the policy while avoiding confusion among researchers, policymakers, and the public. Clear, scientifically grounded terminology is particularly important to maintain public understanding and confidence in emerging biomedical technologies.

2. **Structure of tiered oversight (i.e., Federal, institutional, and investigator), including appropriateness in terms of calibration to risk, accountability measures, transparency, and streamlining of administrative burden, etc.**

Allowing certain activities to undergo delegated Institutional Biosafety Committee (IBC) review could reduce unnecessary administrative burden while maintaining appropriate safety protections. As NIH considers this approach, ASGCT encourages the Institutes to ensure that oversight requirements reflect the actual risks of individual technologies and research activities. CGT research encompasses a broad range of approaches, including viral vectors, genetically modified cells, and other emerging platforms with distinct characteristics and safety profiles.[3,4] Oversight requirements should account for established scientific evidence, prior safety data, and modifications specifically designed to reduce risk, ensuring that the level of review is proportional to the risks of the research – rather than determined solely by broad technology classifications.

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[2] National Institutes of Health, Office of Science Policy (2026 August). *Draft NIH Biosafety Policy for Research Involving Biohazards [NOT-OD-26-112].* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
[3] Ay, C., Reinisch, A. (2025 May). Gene therapy: principles, challenges and use in clinical practice. *Wien. Klin. Wochenschr. 137*(9-10):261-271 https://pubmed.ncbi.nlm.nih.gov/38713227/
[4] Lemmens, M., Dorsheimer, L., Zeller, A., Dietz-Baum, Y. (2024 May). Non-clinical safety assessment of novel drug modalities: Genome safety perspectives on viral-, nuclease- and nucleotide-based gene therapies. *Mutat. Res. Genet. Toxicol. Environ. Mutagen. 896.* https://pubmed.ncbi.nlm.nih.gov/38821669/

ASGCT also encourages NIH to clarify how the proposed oversight framework would interact with existing institutional and FDA requirements for CGT clinical research.[5] Clear expectations and coordination across oversight bodies will be important to avoid unnecessary duplication or delays while maintaining rigorous safety standards.

4. **Effectiveness of compliance and enforcement mechanisms for ensuring biosafety, including strategies for encouraging voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions), and addressing any biosecurity challenges.**

ASGCT recognizes the importance of institutional accountability and appropriate enforcement mechanisms to maintain strong biosafety standards. However, the proposed policy's broad scope, coupled with provisions allowing noncompliance to affect current and future NIH funding, raises concerns about the potential consequences of unclear or inconsistently interpreted requirements.

The proposal states that institutions receiving NIH funding must ensure compliance for research conducted or sponsored by the institution, regardless of the individual research project's funding source. It further provides that noncompliance may result in additional funding conditions, termination of awards, or impacts on future funding decisions. Biomedical research programs often require years of continuous effort before meaningful outcomes can be achieved. Long-term preclinical studies, specialized manufacturing facilities, multi-year clinical trials, longitudinal patient follow-up, and complex public-private partnerships cannot be paused and restarted without serious impact on patient participants and institutions. For CGTs, where a single program may span a decade from IND filing to BLA approval,[6,7] mid-stream terminations do not merely delay results. They can end programs entirely. Although similar institutional compliance obligations and funding-related enforcement mechanisms exist under the current Guidelines, the expanded scope of the proposed policy, coupled with the longer development timelines associated with CGTs, makes it especially important that institutions have a clear understanding of their responsibilities.

Without sufficient detail regarding how the new requirements will be interpreted and enforced, researchers and institutions may face uncertainty about whether established practices remain compliant. This uncertainty could discourage research activities, create unnecessary administrative burden, or disrupt ongoing projects, even where there is no meaningful change in biosafety risk. Nearly every FDA-approved CGT available to patients today traces its origins to decades of federally supported scientific research.[8] Maintaining consistency and predictability in

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[5] Food and Drug Administration (2026). *Cellular & Gene Therapy Guidances.* https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/cellular-gene-therapy-guidances

[6] Elsallab, M., Ouvina, M., Arfe, A., Bourgeois, F. (2024) Mapping the Clinical Development Trajectory of Cell and Gene Therapy Products. *Clin Pharmacol Ther 117*(5). https://pmc.ncbi.nlm.nih.gov/articles/PMC12447590/

[7] Lapteva, L., Purohit-Sheth, T., Serabian, M., Puri, R. (2020 October). Clinical Development of Gene Therapies: The First Three Decades and Counting. *Mol Ther Methods Clin Dev*. https://pmc.ncbi.nlm.nih.gov/articles/PMC7658574/

[8] Cleary, E., Jackson, M., Zhou, E., Ledley, F. (2023 April) Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019. *JAMA 28*(4). https://pmc.ncbi.nlm.nih.gov/articles/PMC10148199/

federal research funding is essential to sustain the basic research that has helped produce today's pipeline of more than 4,400 therapies.[9]

ASGCT therefore encourages NIH to establish clear, consistent, and transparent compliance standards *before* implementing any new policy. Enforcement should be proportional to the nature and severity of a violation, with appropriate opportunities for institutions to identify and correct deficiencies. An explicit appeals process would help mitigate some of the uncertainty around the policy's implementation. Given that the detailed examples and guidance in the current Guidelines would be removed, NIH should ensure that any appeals process is clearly defined and fully transparent. NIH should also clarify how compliance concerns involving individual research activities would be evaluated and ensure enforcement actions do not unnecessarily jeopardize unrelated programs or funding under an institution's broader research portfolio.

These safeguards would help ensure that biosafety oversight remains focused on protecting researchers and the public while providing institutions with the predictability needed to plan and conduct biomedical research.

5. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

ASGCT is concerned that the proposed policy substantially reduces the level of detail contained in the Guidelines. Currently, there are extensive examples, definitions, and specific requirements that researchers and institutions have relied upon to determine appropriate biosafety practices. While a more streamlined policy may offer some benefit, removing this detail without providing comparable guidance could create uncertainty regarding how established research activities will be evaluated under the new framework.

For CGT researchers, this uncertainty may be particularly consequential given the diversity of technologies and research approaches used across the field. ASGCT encourages NIH to retain or replace the practical examples and technical guidance provided under the existing Guidelines, including clear explanations of how the new requirements apply to research already being conducted. Broad or opaque application of the new guidelines may discourage institutions from undertaking ambitious, high-investment projects. It could make it harder to attract partnerships that translate federal discoveries into domestic manufacturing. The more limited detail in this new policy could be particularly damaging to emerging investigators and early-career scientists, who may require more guidance on emerging technologies and best practices. In particular, NIH should issue implementation resources that clarify whether and how established research practices will be affected by the transition to the new policy.

Finally, ASGCT reemphasizes the importance of providing sufficient implementation guidance *before* the new policy takes effect. We encourage NIH to make these materials available for public review before finalizing or implementing the policy, particularly where they will determine how existing research practices are classified and overseen. Detailed examples, frequently asked questions, and guidance addressing common CGT research activities would help

[9] American Society of Gene and Cell Therapy, Citeline (2026). Gene, Cell, & RNA Therapy Landscape Report: Q2 2026 Quarterly Data Report. https://www.asgct.org/uploads/files/general/Final-ASGCT-Citeline-Q2-2026.pdf

institutions prepare for the transition. NIH should also consider whether the proposed six-month implementation period provides sufficient time for institutions to evaluate existing research, update procedures, and ensure compliance without interrupting ongoing studies.

Conclusion

ASGCT recognizes NIH's efforts to modernize biosafety oversight and the importance of maintaining appropriate protections for researchers, patients, and the public. Any updated framework should provide clear, scientifically grounded expectations that reflect advances in biomedical research - while allowing established and emerging technologies to be evaluated according to their actual risks.

As NIH reviews feedback on the proposed new policy, ASGCT urges the agency to clarify the definition of genetic modification, preserve practical guidance for established research activities, and establish transparent, proportional compliance and enforcement expectations. We further encourage NIH to engage with researchers, institutional biosafety professionals, and other stakeholders to ensure that the final policy and accompanying implementation resources are clear, workable, and supportive of continued scientific innovation.

ASGCT appreciates the opportunity to provide these comments and looks forward to continued engagement with NIH on policies that support safe, responsible, and innovative biomedical research. If you would like to hear more from ASGCT's member experts, please reach out to Caitlin McCombs, ASGCT's public policy manager at cmccombs@asgct.org.

Sincerely,

David Barrett, JD, MS
Chief Executive Officer
American Society of Gene and Cell Therapy

451. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definition of the IBC is not clear, nor is where in the institution it should be house and who at the institution has responsibility and oversight. Who is the AOR and what qualifications do they need? What responsibility or liability of the AOR? Is this a personal liability or that of the institution?

Also, what is GDMO? This is defined nowhere in the proposal. Please make sure all acronyms are spelled out at least once and new or jargon language is defined.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Minor spills of low-risk agents, that do not involve a breach of containment and that were properly cleaned and decontaminated, generally do not need to be reported. What is the volume of a spill is more than "minor spill" that would now have to be reported? Is any spill small enough to be cleaned up by the lab or housekeeping considered minor? At what point is a spill not minor? What is breach of containment, what containment is considered here, a biosafety cabinet, a tube, a room with directional air-flow?

6. Other feedback relevant to this resource: A 6 month implementation period is not feasible! 6 months to roll the new policy requirements into our current registration systems, even if us biosafety professionals were to work on this and nothing else is just not attainable. Working just on this update would probably take more like a year or longer. However, we all have daily job tasks that have to been completed. Implementing the new policy and updating system will take 2+ years.

452. Anonymous

I am responding: On behalf of myself

Name: Anonymous

Name of Organization: Anonymous

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Clinical Human Gene Trials

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Clinical Research Section: mRNA vaccine clinical trials should be exempt as should well established platforms such as the CAR-T clinical trials that are well established.

453. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The registration of a genetic modification into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means is not practical nor does it serve any purpose to strengthen biosafety. A researcher may not even be aware that a passage of a cell has made a genetic modification. Sometimes these modifications will kill the cell or the virus outright and can't be documents. Sometimes they destroy the function of the organism and are therefore trashed. How can something that no longer exists or only exists a short time be captured in a registration? Genetic modification by chemical or radiological means is not currently under the prevue of biosafety. If the policy is to keep this requirement, will the government provide education and instruction to biosafety professionals on assessing such modifications, since many in the field do not have a strong chemistry background or have used radiation?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The mandatory use of a meeting minutes template appears to be regulatory overreach. IBCs have successfully exercised local oversight, accountability, and self-governance for decades. Any concerns with government labs should not be overlayed on academic institutions. Academic institutions should retain flexibility in how they document committee deliberations, provided required elements are captured. This shifts away from a performance-based approach toward unnecessarily prescriptive administrative requirements with little clear benefit to biosafety and biosecurity. Additionally, one size does not fit all and one mandatory template will not work for small and large institutions, private companies, etc.

6. Other feedback relevant to this resource: N/A

454. Jennifer Ramil

I am responding: On behalf of myself

Name: Jennifer Ramil

Name of Organization: Sanford Burnham Prebys

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: JR-Comments-on-the-Draft-NIH-Biosafety-Policy.docx

To whom it may concern:

I appreciate the opportunity to comment on the proposed NIH Biosafety Policy for Research Involving Biohazards. As an institutional biosafety professional and Chair of an Institutional Biosafety Committee, I support NIH's efforts to modernize biosafety oversight and establish a more comprehensive, risk-based framework for biological research.

However, I have significant concerns that several provisions of the proposed policy could unintentionally undermine effective biosafety programs by increasing administrative oversight of routine research and, more importantly, discouraging open communication between researchers and institutional biosafety professionals.

Public Incident Reporting and the Potential Impact on Safety Culture

My greatest concern with the proposed policy is the requirement for institutions to publicly post biosafety incident reports, including reports for incidents that do not meet the threshold for reporting to NIH.

In my experience, one of the most important elements of an effective biosafety program is the relationship between the biosafety office and the research community. Researchers need to feel comfortable contacting Safety when something goes wrong, when they have a question, or when they are uncertain whether an incident presents a potential hazard.

I work to foster an environment where researchers view the biosafety office as a resource and partner rather than simply a regulatory enforcement function. I want researchers to contact us when they experience an exposure, spill, procedural error, equipment failure, or near miss. These conversations provide opportunities to evaluate risks, implement corrective actions, and prevent future incidents.

I am deeply concerned that the proposed public incident-reporting requirements could damage this relationship.

The proposed reporting template includes the Principal Investigator's name and associated NIH grant information. Although individual laboratory personnel should not be identified, the PI's identity and funding information would generally remain publicly available.

I worry that researchers will become reluctant to report incidents if they believe doing so could result in a public report identifying their PI, research program, and grant funding.

Even when an incident is appropriately managed and does not involve negligence or serious noncompliance, public disclosure may create reputational concerns or perceived consequences for future funding.

These concerns may be particularly significant for graduate students, postdoctoral researchers, and other laboratory personnel who may hesitate to report an incident if they believe it could negatively affect their PI or laboratory.

From a biosafety perspective, this is exactly the opposite of the reporting culture we should be encouraging.

I am particularly troubled by the requirement to publicly post incident reports for lower-risk incidents that do not require reporting to NIH. If an institution has appropriately reviewed an incident, evaluated the potential hazards, and implemented corrective actions, I question what additional safety benefit is achieved by requiring the institution to publicly identify the investigator and research program involved.

I strongly support transparency, accountability, and sharing lessons learned from biosafety incidents. However, I do not believe that publicly identifying individual investigators and institutions is necessary to achieve those objectives.

I recommend that NIH establish a centralized, de-identified national biosafety incident reporting database instead of requiring institutions to publicly post individually identifiable incident reports.

Institutions could submit standardized incident reports to NIH, including information necessary for regulatory oversight and investigation. NIH could then make de-identified incident information publicly available through a searchable national database.

Such a database could include incident types, biological agents involved, contributing factors, root causes, containment failures, corrective actions, and lessons learned, while removing institutional names, investigator identities, and grant identifiers.

I believe this would be an incredibly valuable resource for the biosafety community. Biosafety professionals could review incidents from across the country, identify recurring problems, evaluate effective corrective actions, and use this information to improve their own institutional programs.

Currently, valuable lessons learned from laboratory incidents are often limited to the institutions where they occurred. A centralized national database could meaningfully improve the sharing of this information and help prevent similar incidents elsewhere.

More importantly, this approach would support transparency and collective learning without creating unnecessary disincentives for researchers to report incidents to their biosafety offices.

We should be creating policies that encourage researchers to report more incidents, not policies that may make them think twice before contacting Safety.

Expansion of IBC Oversight and the Definition of Genetic Modification

I support expanding biosafety oversight beyond recombinant and synthetic nucleic acid research when additional biological hazards warrant institutional review.

However, I am concerned that the proposed scope is overly broad and not consistently aligned with the subsequent categories of research requiring full IBC review.

The proposed definition of genetic modification includes stable alterations to the genome resulting from passaging, reassortment, chemical treatment, or radiological means.

These methods are used in a wide range of biomedical research activities, many of which have historically been considered routine laboratory research.

While some modifications may increase biological hazards, others do not meaningfully change the risk associated with the biological material.

Under the proposed framework, it appears that a significant amount of research involving these modifications could require full IBC review rather than delegated review, even when the research presents relatively low biological risk.

I am concerned that this is inconsistent with NIH's stated objective of reducing administrative burden for lower-risk research.

From a practical standpoint, expanding full committee review to encompass substantially more routine research will increase the workload for investigators, biosafety offices, and volunteer IBC members.

More importantly, it may divert attention and resources away from research presenting more significant biological hazards.

I encourage NIH to clarify the distinction between genetic modifications that create meaningful changes in biological risk and those that do not.

The level of IBC oversight should be based on the actual biological hazards associated with the research, rather than the method used to produce a genetic modification.

I also recommend that NIH clarify the relationship between the full committee and delegated review categories so that research specifically eligible for delegated review is not inadvertently captured by a broader full committee classification.

Administrative Burden and Three-Year Approval Periods

The proposed policy would substantially increase the amount of research requiring IBC registration and review. Investigators would need to provide more comprehensive descriptions of their biological research activities, and institutions would need to expand their registration and oversight systems.

I am concerned that this additional administrative burden will not necessarily translate into improved laboratory safety.

I am also concerned about the proposed requirement that IBC approvals not exceed three years, followed by de novo registration and review.

At my institution, IBC protocols are currently approved for five years, with amendments reviewed when research activities or biological hazards change.

Requiring a new submission every three years, even when the research has not materially changed, will increase the administrative workload for both investigators and IBCs.

I recognize the importance of periodic review, but I believe that oversight should be proportionate to risk.

For established, lower-risk research, I encourage NIH to consider longer approval periods or streamlined renewal procedures, while continuing to require review of significant changes that may affect the original risk assessment.

Biosafety professionals and IBC members have limited time and resources. I believe those resources are most effectively used evaluating new hazards, changes in research activities, and higher-risk experiments rather than repeatedly reviewing unchanged research solely to satisfy an administrative renewal requirement.

Public Meeting Minutes and Risk Assessment Information

I support transparency in IBC decision-making and recognize the public's interest in understanding how institutions oversee biological research.

However, I am concerned about the level of detail required in the proposed public meeting-minutes template, particularly the requirement to include detailed risk assessments and descriptions of experimental manipulations.

IBC members need access to comprehensive information to conduct meaningful risk assessments. However, I do not believe that all of this information necessarily needs to be included in publicly accessible meeting minutes.

Institutions should maintain detailed internal records documenting their risk assessments, discussions, and approval decisions. Public meeting minutes should demonstrate that appropriate oversight occurred without requiring unnecessary disclosure of detailed experimental information.

I encourage NIH to provide greater flexibility regarding the level of technical detail included in public meeting minutes and clearer guidance on appropriate redactions.

Implementation Timeline

Finally, I am concerned that the proposed six-month implementation period is insufficient given the magnitude of the changes.

Institutions will need to revise their biosafety policies, IBC procedures, protocol registration systems, review categories, incident-reporting practices, and public disclosure processes. Researchers and committee members will also need training on the new requirements.

I encourage NIH to consider a phased implementation period of at least 24 months and to provide comprehensive guidance, practical examples, and standardized resources to support the transition.

I also encourage NIH to consider issuing a revised draft for additional public comment, particularly to address the ambiguities surrounding the scope of covered research and the distinctions between full committee and delegated review.

Conclusion

I appreciate the NIH’s efforts to modernize biosafety oversight and recognize the importance of maintaining strong institutional biosafety programs.

However, I encourage NIH to consider how the proposed policy will function in practice and whether the additional requirements will meaningfully improve laboratory safety.

As a biosafety professional, I believe effective oversight requires more than comprehensive regulations and documentation. It requires relationships,

communication, trust, and the willingness of researchers to engage openly with institutional biosafety personnel.

My greatest concern is that the proposed public incident-reporting requirements could undermine those relationships and discourage researchers from reporting the very incidents that biosafety professionals need to know about.

I strongly support establishing a centralized, de-identified national biosafety incident database that would allow institutions to learn from incidents across the research community without publicly identifying individual investigators and institutions.

I also encourage NIH to ensure that the final policy is genuinely risk-based, provides appropriate opportunities for delegated review, and avoids imposing unnecessary administrative requirements on routine biological research.

Ultimately, I believe the success of this policy should be measured not by the volume of research registrations, committee reviews, or publicly posted reports, but by whether it helps institutions identify hazards, prevent incidents, and foster a research environment where safety concerns are openly communicated and effectively addressed.

Thank you for considering these comments.

Sincerely,

Jennifer Ramil, MBA, RBP (ABSA)
Director of Environmental Health and Safety
IBC Chair
Sanford Burnham Prebys
10901 N Torrey Pines Road
La Jolla, CA 92037
jramil@sbpdiscovery.org
858-646-3140

455. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Labs use long lists of human cells lines in their research. The proposed policy requires the registration of genetic modifications introduced into cells by passaging, reassortment, chemical or radiological means. The effort it would take to register every last cell line under this scope far outweighs any benefit this would have to oversight and safety. To understand and asses the nuanced differences between all these genetic variations would take a tremendous amount of time and education for biosafety professional and IBC members when the risk of any human cell line remains the same for one cell line to another. Performing a comprehensive risk assessment prior to initiating research involving these human cells, when this work has already been going on for decades but was never captured in an IBC registration, would also be a burden that far exceeds any benefit. What is the risk assessment of any human cell line beyond what is required under OSHA's BBP Standard? There are already mechanisms and guidance in place for working with this material and no further registration is required.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

456. Sanford Burnham Prebys

I am responding: On behalf of an organization

Name: Jennifer Ramil

Name of Organization: Sanford Burnham Prebys

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Institutional-Comments-on-the-Draft-NIH-Biosafety-Policy.docx

Sanford Burnham Prebys – Institutional Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

Sanford Burnham Prebys (SBP) appreciates the opportunity to provide comments on the Draft NIH Biosafety Policy for Research Involving Biohazards. We support NIH's efforts to modernize biosafety oversight, strengthen institutional accountability, and establish a more comprehensive, risk-based framework for the safe conduct of biomedical research.

SBP recognizes the importance of maintaining effective biosafety oversight as research technologies and biological hazards continue to evolve. We also appreciate NIH's stated goal of reducing unnecessary administrative burden for lower-risk research while focusing institutional oversight on activities presenting meaningful biosafety risks.

However, we are concerned that several provisions of the proposed policy may have unintended consequences, including substantially expanding IBC oversight of routine biological research, increasing administrative requirements for investigators and institutions, and potentially discouraging the reporting of laboratory incidents.

Our primary recommendations are outlined below.

Public Disclosure of Incident Reports and the Potential Impact on Institutional Safety Culture

SBP's most significant concern is the proposed requirement for institutions to publicly post biosafety incident reports, including incidents that are reported to NIH and lower-risk incidents that are reviewed by the IBC but do not require NIH reporting.

Effective institutional biosafety programs depend upon open communication, collaboration, and trust between researchers and biosafety professionals. Researchers must feel comfortable promptly reporting exposures, spills, containment failures, procedural errors, near misses, and other potential safety concerns. These reports allow institutional biosafety professionals and IBCs to provide immediate assistance, evaluate potential hazards, identify root causes, implement corrective actions, and prevent future incidents.

We are concerned that mandatory public disclosure of incident reports could fundamentally alter this relationship.

The proposed incident-reporting template requires identification of the Principal Investigator and associated NIH grant information. Although individual laboratory personnel should not be identified, the PI's identity and funding information would generally remain publicly available.

Public disclosure of this information may create reputational or funding concerns for investigators, even when incidents are promptly reported, appropriately managed, and do not result from negligence or significant noncompliance. Investigators may reasonably perceive that reporting an incident could negatively affect their professional reputation, future funding opportunities, or the public perception of their research programs.

More importantly, these concerns could discourage researchers from voluntarily reporting incidents to institutional biosafety offices. We believe this represents a potentially serious unintended consequence of the proposed policy.

A strong safety culture encourages researchers to report concerns early, including incidents that may initially appear minor or for which the actual risk is uncertain. Institutional biosafety programs rely on these communications to identify emerging hazards and prevent more serious incidents. If researchers become concerned that contacting their biosafety office could ultimately result in a publicly posted incident report identifying their PI and grant information, they may become less willing to report events.

We are particularly concerned about the requirement to publicly post reports for lower-risk incidents that do not meet NIH reporting thresholds. Requiring public disclosure of these incidents may discourage reporting without providing a corresponding improvement in biosafety oversight.

Recommendation:

SBP strongly recommends that NIH reconsider the requirement for institutions to publicly post individually identifiable incident reports, particularly those involving lower-risk incidents that do not require NIH reporting.

Instead, we recommend that NIH establish a **centralized, de-identified national biosafety incident reporting database.**

Under this approach, institutions would submit standardized incident information to NIH, and NIH would maintain a publicly accessible database that removes institutional names, investigator identities, personnel identifiers, and grant information.

The database could include information such as:

- Biological agents and research activities involved;
- Types of incidents and potential exposures;
- Contributing factors and root causes;
- Containment failures or equipment issues;
- Corrective and preventative actions; and
- Lessons learned and recommendations for preventing similar incidents.

We believe this approach would provide significantly greater value to the biosafety community than requiring individual institutions to post incident reports on their respective websites.

A centralized national database would allow biosafety professionals, IBCs, researchers, and NIH to identify recurring incident types, emerging hazards, common contributing factors, and effective corrective actions across institutions. Such a response could directly inform institutional training, risk assessments, standard operating procedures, and prevention strategies.

Importantly, this approach would promote transparency and shared learning while preserving the collaborative relationship between researchers and institutional biosafety professionals.

We encourage the NIH to prioritize a reporting framework that supports learning and prevention rather than one that may inadvertently discourage incident reporting.

Expanded Scope of the Policy and Consistency with Risk-Based Oversight

SBP supports expanding biosafety oversight to address biological hazards that may not be adequately covered by the current NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

However, we are concerned that the proposed policy's broad scope is not consistently reflected in its subsequent review and oversight requirements.

In particular, the proposed definition of genetic modification includes stable alterations to the genome resulting from passaging, reassortment, chemical treatment, or radiological means.

These techniques are used in a wide variety of biomedical research activities, including routine cell culture, experimental selection, and the development of research models. While certain modifications may increase biological hazards and warrant additional oversight, not all such modifications result in an increased biosafety risk.

When this broad definition is considered alongside the proposed categories requiring full IBC review, it appears that a substantial amount of routine biological research could become subject to full committee review rather than delegated review.

This outcome would appear inconsistent with NIH's stated objective of reducing unnecessary administrative burden for low-risk research.

We are concerned that requiring full committee review based primarily on the method of genetic modification, rather than the resulting biological hazard, could divert limited IBC resources away from research presenting more significant risks.

Recommendation:

We recommend that NIH clarify the relationship between the definition of genetic modification and the categories of research eligible for full committee or delegated review.

Specifically, NIH should establish clear criteria distinguishing modifications that introduce or increase a meaningful biological hazard from modifications that do not materially change the risk profile of the organism or research activity.

Research involving genetic modifications that do not increase pathogenicity, transmissibility, host range, environmental persistence, toxicity, or other relevant biological hazards should be eligible for delegated review or another proportionate oversight pathway.

We also recommend that NIH provide additional examples and decision-making guidance to assist institutions in consistently assigning research to the appropriate review category.

The level of IBC oversight should be determined by the potential biological risk of the proposed research rather than the technique used to generate a biological modification.

Increased Administrative Burden and Protocol Approval Duration

The proposed policy would substantially increase administrative responsibilities for investigators, institutional biosafety offices, and IBC members.

By expanding the scope of covered research, institutions may need to register and review a significantly larger proportion of their biological research activities.

Principal Investigators would be required to provide more comprehensive information about their research activities, biological materials, experimental manipulations, and associated risk assessments. Institutions may also need to substantially restructure their existing IBC registration systems to ensure that all covered activities are appropriately documented and reviewed.

Additionally, the proposed policy limits IBC approval periods to no more than three years and requires de novo registration and review at the end of the approval period.

SBP currently maintains a five-year IBC protocol approval cycle, with additional oversight of higher-risk research and review of amendments as appropriate.

Requiring de novo review every three years would increase the frequency of protocol submissions, administrative processing, and committee review, including for established research activities that have not materially changed and do not present increased biosafety risks.

We recognize the importance of periodic review and ensuring that approved research remains consistent with current biosafety practices. However, we question whether requiring a new review of otherwise unchanged, lower-risk research every three years provides a corresponding improvement to biosafety.

Recommendation:

We recommend that NIH allow institutions greater flexibility in establishing protocol approval periods based on the risk associated with the research.

For lower-risk research, NIH should consider permitting longer approval periods, streamlined renewals, or delegated review of continuing research that has not materially changed.

Institutions should retain responsibility for reviewing significant amendments, changes in biological hazards, containment requirements, or experimental procedures that could affect the original risk assessment.

We believe this approach would preserve appropriate oversight while allowing investigators and IBCs to focus their resources on research presenting meaningful biosafety risks.

Public Meeting Minutes and Disclosure of Research Risk Assessments

SBP recognizes the importance of transparency in institutional biosafety oversight and supports making appropriate information about IBC activities available to the public.

However, we are concerned that the proposed meeting-minutes template requires extensive details regarding individual research protocols, biological agents, experimental manipulations, and associated risk assessments to be included in publicly accessible meeting minutes.

These requirements could result in public disclosure of detailed research information that may be scientifically sensitive, preliminary, or potentially subject to misinterpretation without appropriate context.

We recognize that the draft policy allows redaction of certain protected information. However, the proposed limitations on redaction may not adequately address the concerns associated with publishing detailed experimental risk assessments.

We are also concerned that requiring extensive protocol-specific information in public meeting minutes may increase administrative workload and shift committee attention toward documentation requirements rather than substantive evaluation of biosafety risks.

Recommendation:

We recommend that NIH distinguish between the detailed documentation necessary for effective IBC review and the level of information necessary to demonstrate appropriate institutional oversight to the public.

Institutions should maintain comprehensive internal records documenting risk assessments, committee discussions, and approval decisions.

Public meeting minutes should provide sufficient information to demonstrate that the IBC evaluated the relevant hazards, establishing appropriate containment measures, and made an informed approval decision, without requiring disclosure of unnecessary experimental details.

NIH should also provide clearer guidance regarding the appropriate redaction of sensitive research information and allow institutions reasonable discretion to protect legitimate research confidentiality and security interests.

Implementation Timeline and Institutional Resources

The proposed policy represents a substantial change to the current NIH biosafety oversight framework.

Implementation will require institutions to evaluate and revise existing biosafety policies, IBC procedures, protocol registration systems, review classifications, reporting processes, training programs, and public disclosure practices.

Institutions may also need to increase administrative support and committee resources to accommodate the expanded scope of research requiring IBC review.

We are concerned that the proposed six-month implementation period may not provide sufficient time for institutions to make these changes effectively, particularly if NIH does not release detailed implementation guidance and standardized resources until after the policy is finalized.

Recommendation:

We recommend the NIH consider a phased implementation period of at least 24 months, accompanied by clear guidance, standardized templates, and practical examples demonstrating how the new policy should be applied.

We also encourage NIH to consider publishing a revised draft for additional public comment after addressing the questions and ambiguities identified by institutions and professional biosafety organizations.

A longer implementation period would allow institutions to establish consistent oversight processes, provide appropriate training to investigators and committee members, and transition existing research registrations without unnecessary disruption to ongoing research.

Conclusion

SBP supports NIH's efforts to modernize biosafety oversight and establish a more comprehensive, consistent, and risk-based approach to managing biological hazards in biomedical research.

However, we encourage NIH to carefully consider the potential unintended consequence of the proposed policy, particularly the substantial expansion of IBC oversight, the increased administrative burden associated with routine research activities, and the effects of mandatory public incident disclosure on institutional safety culture.

Of these concerns, we believe the proposed public incident-reporting requirements warrant particular reconsideration.

Effective biosafety programs depend on researchers being willing to report incidents, ask questions, and seek assistance from institutional biosafety professionals. Policies that inadvertently discourage these interactions may undermine the very safety objectives they are intended to advance.

We strongly encourage NIH to establish a centralized, de-identified national biosafety incident reporting system that promotes transparency, shared learning, and prevention while protecting the collaborative reporting culture essential to effective institutional biosafety oversight.

We further recommend that NIH clarify the scope of covered research, ensure that oversight requirements remain proportionate to actual biological risks, provide greater flexibility for lower-risk research, and allow institutions adequate time to implement the new framework.

We appreciate NIH's consideration of these comments and its continued engagement with the biosafety community.

457. BCM

I am responding: On behalf of an organization

Name: Connor Cordray

Name of Organization: BCM

Type of Organization: Academic Institution

Role: Other

Role - Other: BSO

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): IBC

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft states that it covers all biomedical research in laboratory settings involving biohazards, but it does not define "biohazard" as a standalone term. Instead, the operative scope combines a human-health risk threshold with specified categories of biological materials. This creates uncertainty regarding materials that may principally affect animals, plants, agriculture, or the environment and creates tension with provisions requiring IBCs to assess environmental and population-level effects. NIH should define "biohazard" and clearly state whether risks to animal health, plant health, agriculture, and the environment are within scope, outside scope, or addressed through another federal framework. The final policy should also include a comprehensive glossary defining terminology that determines policy applicability, oversight requirements, and reporting obligations.

The exclusion of genetically modified plants and plant pathogens that do not cause human disease may reduce duplicative oversight, but the draft continues to assign IBC responsibilities for environmental risk and references animal and plant health requirements in other contexts. NIH should explicitly address contained greenhouse work, plant-associated microorganisms, genetically modified plant pathogens, animal-only pathogens, and research involving agricultural animals. The final policy should also explain when oversight by USDA or another federal agency satisfies NIH policy requirements and when concurrent NIH or institutional oversight remains necessary.

The final policy should also clarify the organizational boundaries of an "institution" when applying the policy to non-NIH-funded research. This is particularly important for institutions operating across multiple campuses, affiliated hospitals, separately incorporated entities, shared research environments, external research sites, or shared IBC arrangements. Responsibility should also be clearly defined when more than one institution conducts, sponsors, or provides oversight for covered research.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): To better calibrate oversight to risk, commercial transgenic animals maintained at ABSL-1, low-risk plasmids, replication-

incompetent non-integrating vectors expressing low-risk transgenes, well-characterized cell lines, and genetically modified RG1 organisms should be eligible for administrative review or exemption, as appropriate based on risk, rather than automatically requiring full IBC member review. Institutions should be permitted to use a documented screening process to determine whether the work presents minimal biosafety risk. NIH should establish an administrative registration pathway while allowing institutions to elevate individual registrations for IBC review when local circumstances or the institutional risk assessment warrant.

NIH should also create a searchable national repository of NIH containment determinations and risk classifications and define substantial equivalence, permissible deviations, documentation expectations, and responsibility for determining whether a prior determination applies. Where the policy permits publication of approved lower-containment determinations, NIH should clarify whether and under what conditions another institution may rely upon an existing determination.

3. Continued utility of Risk Groups: A universal minimum of BSL-2 for GDMOs does not readily map to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. NIH should allow risk-based equivalent containment approaches and provide technology- and system-specific guidance.

NIH should also clarify the role of Risk Group classifications in determining oversight. Risk Group should inform, but not substitute for, an experiment-specific risk assessment. Risk Group classifications should not be treated as equivalent to a required Biosafety Level, IBC review category, or containment determination. Oversight and containment decisions should consider the biological material, experimental procedures, quantity and concentration, routes of exposure, host characteristics, engineering controls, and potential consequences of release.

Influenza provisions should also specify which gene segments, combinations or proportions of genetic material, phenotypic characteristics, and virus types trigger enhanced BSL-3 containment, rather than using language that could be interpreted to apply broadly to constructs containing any listed influenza segment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The draft states that research also under another federal agency's regulation or purview "may proceed under the oversight of the other federal agency" once applicable approvals or clearances have been obtained. Elsewhere, however, the policy contemplates institutional and regulatory approvals operating concurrently. The final policy should clearly distinguish circumstances in which another federal agency's oversight substitutes for NIH federal review from those in which institutional requirements, including IBC review, biosafety oversight, and incident reporting, remain applicable.

NIH should also clarify the qualifications, authority, and institutional support expected for the Biological Safety Officer or other official assigned these responsibilities. These expectations should be commensurate with the institution's research portfolio and risk profile rather than based solely on the presence of BSL-3, BSL-4, or gene drive research.

Institutions should retain flexibility to determine appropriate qualifications based on education, training,

experience, and demonstrated biosafety competency. Professional credentials, such as the Registered Biosafety Professional and Certified Biological Safety Professional, may provide evidence of competency but should not be established as mandatory qualifications. NIH should also recognize that effective implementation will require adequate institutional authority, staffing, resources, access to relevant research spaces and records, and the ability to elevate unresolved risks to institutional leadership.

Mandatory public posting of detailed IBC minutes and incident reports raises legitimate concerns regarding proprietary research information, personal privacy, research security, biosecurity, and the potential identification of individual researchers. Although the draft recognizes certain allowable redactions, additional standards are needed to ensure consistent application across institutions and to avoid disclosure of information that could create security or biosecurity risks.
Public reporting requirements should also be structured so they do not inadvertently discourage prompt reporting of minor incidents and near misses, which are important components of a strong safety culture. NIH should consider requiring standardized, de-identified public summaries focused on oversight outcomes, corrective actions, and lessons learned, while maintaining detailed records for NIH oversight and other legally required disclosure processes.

NIH should also clarify how public-disclosure requirements are to be reconciled with applicable CDC and USDA biosecurity requirements, particularly for research involving select agents and toxins. The final policy should establish minimum mandatory redaction standards for security-sensitive information, including information that could identify personnel, reveal sensitive facility characteristics, compromise proprietary research, or create personnel or institutional security risks.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft should define “incident,” “release,” “loss of containment,” “basic first aid,” “agent-specific treatment,” “potential exposure,” “compliance violation,” and “minor spill.” The policy should specifically clarify whether precautionary post-exposure prophylaxis constitutes “agent-specific treatment” for reporting purposes.

NIH should also clarify whether any event occurring in a BSL-3 or BSL-4 laboratory is reportable regardless of its relationship to biohazard containment or exposure potential. The policy should distinguish administrative or procedural noncompliance from events presenting an actual or potential biosafety risk.

The reporting framework should be tiered according to risk and consequence. Events involving significant exposure, escape of biological material beyond defined containment boundaries, loss of containment, potential community impact, or other serious biosafety consequences may warrant rapid notification. A facility or equipment failure should not, by itself, be considered a release when functioning redundant systems maintain containment and prevent personnel exposure or environmental release. Administrative noncompliance and lower-risk events should not necessarily require the same reporting timeframe as consequential events.

NIH should consider allowing up to 72 hours for initial reporting of events that do not present an immediate or significant biosafety risk, while retaining a shorter notification requirement for serious events. This would allow institutions sufficient time to gather relevant facts, consult with occupational

health and other involved parties, assess potential exposures, and provide NIH with more accurate and meaningful initial information.

6. Other feedback relevant to this resource: The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, identify the organizational boundaries of covered activities, obtain an approved Biosafety Assurance, revise institutional policies, redesign electronic systems, establish public-facing processes and redaction standards, revise incident-reporting workflows, train affected research communities, secure institutional approvals and resources, or, in some cases, establish an entirely new IBC or biosafety program.

NIH should provide at least 24 months from publication of the final policy and associated implementation materials, with phased implementation milestones and transitional or provisional assurance mechanisms that prevent unnecessary interruption of ongoing research.

NIH should also publish comprehensive implementation guidance, model procedures, standardized templates, decision tools, and examples that institutions can adapt locally. These materials should address scope determinations, institutional boundaries, risk-based review pathways, coordination with other federal agencies, BSO responsibilities, incident classifications, reporting thresholds, public disclosure, and redaction standards.

The implementation materials should be available sufficiently in advance of the effective date to allow institutions to develop, validate, and implement compliant systems and processes. The implementation period should not begin until the final policy and the materials necessary to operationalize it have been issued.

458. Antony Schwartz

I am responding: On behalf of myself

Name: Antony Schwartz

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): All areas of biomedical research affected by the proposed NIH Policy. As a biosafety professional, my response responsibilities span all research domains that require these biosafety and biosecurity oversight measures.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attached.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see attached.

3. Continued utility of Risk Groups: Please see attached.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see attached.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attached.

6. Other feedback relevant to this resource: Please see attached.

459. West Virginia University

I am responding: On behalf of an organization

Name: Joshua Parenti

Name of Organization: West Virginia University

Type of Organization: Academic Institution

Role: Other

Role - Other: Associate Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Medical Sciences

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Draft focused heavily on rDNA, as stated many times already. There's a ton of other biosafety topics that can be discussed. I think maybe having 5 – 10 of the top topics listed and broken down from there, there is just too much to consider in the biosafety world. Obviously need to stay focused on what affects us here and not delve into topics that aren't relevant. I'm sure this will come following comments. Maybe a tiered approach would work, break topics into groups and have a specialist in those areas talk on..??

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): How does this affect our team of 2 at our institution. Again, clarity and actual deliverables are needed. Considering the true scope of our objectives is something we need to stay focused on.

3. Continued utility of Risk Groups: This makes things confusing, I've used them interchangeably in the past but tend to use BSL over RG in trainings. It would be helpful if the NIH would clearly point out the key difference and indicate where/when to use RG vs BSL. At our level we give students the important, relevant info needed to get them started. Are PI's following up at all to add to what we're providing?

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I think voluntary compliance is a good idea and how change needs to begin, but the NIH should be more involved and set deadlines with clear objectives and expectations. We need to be well informed, and info should be readily available and easy to understand. Following implementation, a 6 month and annual follow-up should be required. During the implementation period NIH should be available to answer questions. Clarity, deadlines, guidance, and follow-up.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The templates are good for guidance, but every org. is different and may have different info to include based on their research. Given the publication of this information and the group of individuals it reaches, it should be easy to understand.

6. Other feedback relevant to this resource: Needs to be straight forward in expectations of NIH and labs with clear directives. This is especially true for the biosafety team. I also think it would be helpful to have resources allocated and discussed.

I think change is good, but this change needs to be well documented with guidance. Over time (hopefully ~ 6 months) I think this will be ironed out and maybe the draft was meant to foster conversation on a high level and we'll get into the weeds over time.

Uploaded File: Comments-to-draft-policy-jp-10_19_26.docx

Description: Word document with comment regarding NIH draft

NIH draft comments - JP

1. **Scope of the Policy**

Draft focused heavily on rDNA, as stated many times already. There's a ton of other biosafety topics that can be discussed. I think maybe having 5 – 10 of the top topics listed and broken down from there, there is just too much to consider in the biosafety world. Obviously need to stay focused on what affects us here and not delve into topics that aren't relevant. I'm sure this will come following comments. Maybe a tiered approach would work, break topics into groups and have a specialist in those areas talk on..??

2. **Tiered oversight**

How does this affect our team of 2 at our institution. Again, clarity and actual deliverables are needed. Considering the true scope of our objectives is something we need to stay focused on.

3. **Risk Groups vs BSL**

This makes things confusing, I've used them interchangeably in the past but tend to use BSL over RG in trainings. It would be helpful if the NIH would clearly point out the key difference and indicate where/when to use RG vs BSL. At our level we give students the important, relevant info needed to get them started. Are PI's following up at all to add to what we're providing?

4. **Voluntary Compliance**

I think voluntary compliance is a good idea and how change needs to begin, but the NIH should be more involved and set deadlines with clear objectives and expectations. We need to be well informed, and info should be readily available and easy to understand. Following implementation, a 6 month and annual follow-up should be required. During the implementation period NIH should be available to answer questions. Clarity, deadlines, guidance, and follow-up.

5. **Reporting/templates**

The templates are good for guidance, but every org. is different and may have different info to include based on their research. Given the publication of this information and the group of individuals it reaches, it should be easy to understand.

6. **Implementation resources**

Needs to be straight forward in expectations of NIH and labs with clear directives. This is especially true for the biosafety team. I also think it would be helpful to have resources allocated and discussed.

Other: I think change is good, but this change needs to be well documented with guidance. Over time (hopefully ~ 6 months) I think this will be ironed out and maybe the draft was meant to foster conversation on a high level and we'll get into the weeds over time.

460. duane

I am responding: On behalf of myself

Name: duane

Name of Organization:

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Other

Role - Other: Biosafety Consultant

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: NIH should exempt from the NIH Biosafety Policy all Contract Research Organizations (CROs) and Contract Development and Manufacturing Organizations (CDMOs) that work with client materials and products that fall under the scope of the NIH Biosafety Policy and that were developed by the client with NIH funding. The exemption should not include clinical research as noted in Section IV-2 of the Draft NIH Biosafety Policy whereby such materials and products are administered to human research subjects. CROs perform clinical/commercial quality control testing in a laboratory setting and CDMOs perform scale up and production on behalf of clients. The client, not the CRO or CDMO, should be responsible for compliance with the NIH Biosafety Policy. CROs and CDMOs should be encouraged to adopt the NIH Biosafety Policy as best practice.

NIH should define and limit the breadth of compliance scope as it pertains to large international biopharmaceutical companies where not all sites receive NIH funding for research with biohazards covered under the NIH Biosafety Policy. The NIH Biosafety Policy scope should be limited to only those company sites that perform NIH-funded research. For example, if a biopharmaceutical company has one location at a subsidiary in the United States that receives NIH funding for research with biohazards, only that site should be subject to the NIH Biosafety Policy. The entire subsidiary and potentially the entire company (including non-US sites) should not be in scope for compliance but should be encouraged to adopt the NIH Biosafety Policy as best practice.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: NIH should remove the requirement to publicly identify the PI and the biohazardous material involved in an incident. Identification of the PI in the public domain may have negative consequences such as failure of the PI to report incidents, potentially decreasing the safety culture of the institution. If the PI name is publicly available there is a potential security threat to the institution and the PI, should animal rights activists and others use that information to target the PI and/or the institution. OSHA, for example, does not require the names in required annual posting of the OSHA 300 Log in a workplace. Additionally, in private industry, a full description of the "nature of biohazardous material involved in incident" may expose confidential information that a company may not want to publicly disclose to protect intellectual property.

6. Other feedback relevant to this resource: N/A

461. Mark Endsley, PhD

I am responding: On behalf of myself

Name: Mark Endsley, PhD

Name of Organization: University of Texas Medical Branch

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Disease Immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: NIH-Biosafety-Policy-Comments-1.docx

Draft NIH Biosafety Policy for Research Involving Biohazards
(NIH Guidelines replacement)
Comments will be accepted until **October 19, 2026.**

Submit comments here: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving00-biohazards/

October 27, 2026

RE: Comments for the Draft NIH Biosafety Policy for Research Involving Biohazards (Request for Comment – NOT-OD-26-112, dated August 19, 2026)

To whom it may concern,

I am an infectious disease immunologist in the Department of Microbiology and Immunology, as well as a member of the Institutional Biosafety Committee, with the University of Texas Medical Branch in Galveston, Texas. My comments regarding the Draft NIH Biosafety Policy for Research Involving Biohazards (the Policy) (NOT-OD-26-112, dated August 19, 2026) are below.

I support the replacement of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) with risk-based biosafety oversight. I offer these comments to help NIH develop clear, proportionate, and workable requirements that protect personnel, the public, agriculture, and the environment, while enabling responsible scientific research.

The significant concerns in these comments and raised by the broader scientific community demonstrate that the draft Policy cannot be implemented in its current form. We respectfully request that NIH revise the Policy and publish additional drafts for public comment before final issuance. While we fully support NIH's objective of modernizing biosafety oversight through a risk-based approach, implementing a poorly defined policy will hamper biomedical research, create widespread administrative confusion, lead to unintentional noncompliance, and damage the collaborative relationship among researchers, regulators, and the biosafety compliance community.

1. **Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.**
    a. The stated intention of this policy proposal is to expand the scope of the *NIH Guidelines* while removing red tape for low-risk research. The goal of removing red tape for low-risk research within this Policy has not succeeded. The Draft Policy includes within its scope multiple categories of research that are currently Exempt in the *NIH Guidelines*. For example, research with certain transgenic rodents and certain recombinant work with non-pathogenic *E. coli*; the NIH Director has already determined that these experiments are of such low risk that they were actively designated as Exempt, yet this Policy considers them of high enough risk to require IBC approval. The Policy does not provide reasoning for this change in the risk assessment.
    b. A meaningful administrative burden with the *NIH Guidelines* is the pathway through which NIH OSP will assign a biocontainment level for research with an agent that does not have an assigned RG within Appendix B. This issue could be less burdensome if NIH OSP had been granted authority within the *Guidelines* to assign a risk group to agents that do not have risk groups.
        i. The current approval pathway is limited to the specific PI at a specific entity. Therefore, other PIs at the same entity are similarly required to obtain a biocontainment level from NIH OSP for the same agent.
        ii. **We recommend** that the Policy clearly state that determinations of risk group and/or recommended biosafety levels will apply to all researchers and all entities subject to the Policy.
            1. We understand that there will be differences in the recommended biosafety level due to geography/climate and considerations for research being performed outside the US, which should be considered if this recommended change is made to the Policy.
    c. The Scope of the Policy states “Any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained.”
        i. This statement must be clarified. We appreciate that the Policy seeks to avoid duplicative oversight from multiple federal agencies. However, the statement itself is unclear regarding the oversight, approvals, and clearances that are mentioned.
            1. If a researcher is registered to work with wildtype Nipah virus (RG4, therefore falling under Section IV-2) with the Federal Select Agent Program (FSAP), do they not need to obtain IBC approval for the same work?

2. If a researcher is registered to generate chimeras of paramyxoviruses within a Nipah virus backbone (a novel agent by the current definition, therefore falling under Section IV-1) with FSAP, do they need to obtain NIH and IBC approval for the same work?
3. If an incident occurs in a BSL3 or BSL4 that involves a Select Agent for which the researcher is registered with FSAP, does the incident get reported to NIH and posted on a public facing website?

d. Effective Date
   i. The Policy states that the effective date will be 6 months from publication of the final Policy. This is a very short timeline to implement a Policy with such significant expansions in scope. Implementation of this Policy will require that IBCs ask for more resources from their institutions, obtain those resources, communicate with stakeholders, develop new training, implement training for IBC members and researchers, obtain new software or update software, and make significant choices in how to implement each part of the Policy. Six months is not nearly sufficient, and all entities will struggle.
   ii. This is further complicated by the need to provide a written Biosafety Assurance that has been approved by NIH in order to perform any research after the effective date. Will NIH have the required full-time employees (FTEs) to review and approve hundreds of Biosafety Assurances that will be submitted within that effective date?
   iii. **We recommend** that the effective date be at least 2 years.
e. The Policy uses terms and words but does not define them. The failure to define these words will lead to ambiguity in the interpretation and implementation of the Policy, leading to unintentional noncompliance. Further, some of these words did not have definitions in the *NIH Guidelines* and therefore this is a good opportunity to rectify this issue. These include:
   i. Adventitious agent, organism, transgenic, GDMO, incident, release, potential risk to human health, peptide, shedding
      1. Organism is inconsistently used within the Policy and is not an easily defined word. Replace “organism” with more appropriate and easily definable terms throughout the Policy. Specify bacteria, fungi, archaea, protists, viruses, or animals as needed. If there is a concern about a biological agent that doesn’t fall within those terms, be clear about that (e.g., a biological agent created through synthetic biology that cannot be readily categorized).
f. The Policy omits a review workflow for biological agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL yet cannot reasonably fall within the definition of “emerging, novel, or

zoonotic agents". This is a crippling issue for agents that are currently handled at BSL1 or BSL2, though is also an issue for agents handled at BSL3 and BSL4.

i. Theoretically, these could fall within Section IV-1 (research that requires NIH and IBC approval before initiation). However, the administrative burden on NIH to adequately review this work in a timely manner would be significant (even ignoring the administrative burden on researchers and IBCs to review this work). Additionally, much of this research cannot reasonably fall under the category of "higher risk research", when even research involving RG3 or RG4 wild-type biological agents requires only IBC review in the Policy.
ii. For example, human metapneumovirus, non-polio enteroviruses, human parainfluenza virus 5 (Orthorubulavirus mammalis), and Sendai virus (Respirovirus muris) are not emerging, novel, or zoonotic agents. Yet they lack a risk group in the *NIH Guidelines* and are not mentioned in the BMBL. Will NIH review be required for research with these agents for every entity and researcher that falls in scope of the Policy? If so, how many FTEs will NIH be hiring to accomplish timely reviews?
iii. How will human or animal microbiota be treated in this review workflow? Will research with every member of *Bacteroides*, *Bifidobacterium*, *Akkermansia*, *Ruminococcus*, *Prevotella*, and *Anaerococcus* require NIH review? If so, will a researcher even be able to collect a human or animal sample without being in noncompliance with the Policy?

g. The Policy does not define who has the authority to designate the risk group of an agent.
   i. This is of particular importance with RG1 biological agents, since the Policy explicitly states that wild-type RG1 biological agents are outside the scope of the Policy.
   ii. If the local IBC will have the authority to designate the risk group of an agent, that needs to be stated in the Policy.
   iii. If the NIH will have the authority to designate the risk group of an agent, that needs to be stated in the Policy. In addition, NIH must publish and regularly update the list of biological agents that it designates at different RGs.
h. **Responsibilities of the Institution (Section III-A), related to records retention**
   i. The Policy states "The institution must maintain all IBC records in accordance with Section 8.4.2 of the NIH GPS, which requires recipients of awards to maintain appropriate documentation in accordance with record retention requirements in 2 CFR 200.334, which states "the recipient and subrecipient must retain all Federal award records for <u>three years from the date of submission of their final financial report</u>." (emphasis added).
   ii. The Policy assumes that all IBC records are for projects that are federally funded. The Policy has failed to consider projects that are not federally funded

and therefore will never submit a final financial report. As written, such IBC records may never be disposed of, which is either an oversight or regulatory overreach. **This language must be changed to account for IBC records related to non-federally funded projects.**

i. **Responsibilities of the IBC (Section III-B), related to approval period**
    i. The Policy states “Approval should be granted for a period not to exceed three years, at which time a *de novo* registration submission and review is required.”
        1. The Policy fails to describe how biosafety or biosecurity is increased by limiting research approvals to three years. Researchers continue projects over years and decades, and these projects rarely include changes that significantly increase the risk assessment.
        2. Requiring a specific time frame for approvals is overly burdensome and regulatory overreach. Requiring such a short approval time will greatly increase the administrative burden of the IBC and the researcher for little to no increase in biosafety.
        3. **We recommend that this statement be removed from the Policy.**
        4. If the statement cannot be removed from the Policy, we recommend that the Policy explicitly permit grandfathering of previously approved IBC protocols that have approval periods of greater than three years.

j. **Responsibilities of the IBC (Section III-B), incident reporting**
    i. The Policy does not define “incident” or “release”. We recommend the following definitions:
        1. **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.
        2. **Release (Loss of containment or occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
    ii. The Policy does not define “improper disposition” and throughout this section relies on ambiguous phrases such as “any incident”, “loss of containment”, “significant problems”, and “minor spills … generally do not need to be reported”. Terms like “first aid” and “medical treatment” should be aligned explicitly with OSHA standards.

k. **Responsibilities of the NIH (Section III-D)**
    i. The Policy does not state which person or office within NIH will be responsible for these items. In comparison, the *NIH Guidelines* clearly delineated the responsibilities of the NIH Director and the responsibilities of the NIH Office of Science Policy.

1. Entities can reasonably expect that the response times for the NIH Director and for NIH OSP will be significantly different. Further, NIH OSP is staffed with many subject matter experts, while the NIH Director can never be an SME for every aspect of biomedical science. Therefore, the Policy must clearly state who will be responsible for these duties.
2. **We recommend that the Policy clearly state which person or office is responsible for the duties described in this section.**

2. **Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).**
    a. In general, the tiered oversight is appreciated. The IACUC-style review that specifically permits delegate approval will be a helpful decrease to time commitments from the full IBC for review of lower risk research.
        i. The Policy has replaced two previous categories of review, those requiring NIH Director approval (III-A) and those requiring NIH OSP approval (III-B), with a singular category that requires NIH approval. The Policy does not describe which person or office within NIH will be performing the review and approval of research within Section IV-1. This must be clearly stated in the Policy within the Responsibilities of NIH (III-D).
    b. **General Definitions: *Emerging agent or organism***
        i. The Policy does not state who determines that an agent is an emerging agent. Does the local IBC decide what qualifies as an emerging agent? If not the local IBC, we recommend that NIH develop rapid dissemination notices that are sent to all entities identify emerging agents so that entities can avoid noncompliance.
        ii. The Policy does not describe how an agent or organism goes from being an emerging agent to a non-emerging agent. Will an agent be "emerging" until the first time NIH has reviewed it under Section IV-1? Until it has been assigned a risk group? Until it has appeared in the next edition of the BMBL?
        iii. Does the definition of an emerging agent include a well characterized agent that exhibits a change in pathogenicity or transmission? If this Policy existed at the time, would the recent outbreaks of Zika virus, mpox virus, and Andes virus qualify as "emerging"? Would the label of emerging apply to the agent, or merely to the specific strain of the biological agent?
        iv. If considered now (October 2026), which agents would qualify as "emerging"? Highly pathogenic avian influenza virus H5N1? SARS-CoV-2?
    c. **General Definitions: *Genetic Modification***
        i. This definition is so expansive that it causes internal contradictions within the Policy.
        ii. The definition uses the undefined word "organisms", which is unhelpful. As written, this causes the Policy to confusingly regulate research conducted with <u>genetically modified</u> organisms (Section IV-2) differently from <u>transgenic</u> organisms (Section IV-3) but does not define the difference between the two. We recommend replacing the word organism with the biological agent(s) that are intended to be within scope of the Policy.
        iii. *Can be transcribed or translated:* as written, this will include expression from an RNA vaccine that is administered to an animal or transfected into a cell line. The Policy does not describe how including this as a genetic modification addresses a biosafety concern.

iv. *The introduction … of stable alterations into the genome by passaging, reassortment, chemical or radiological means:* as written, the definition includes unintentional alterations into the genome, such that researchers will become noncompliant with the Policy almost immediately.
    1. Passaging any virus in tissue culture will result in unintentional alterations into the genome.
    2. Cancer research includes work with antineoplastic drugs that would fall within scope of this definition.
    3. **We recommend that this definition be re-written to be limited to intentional stable modifications.**

d. **General Definitions: *Toxin***
    i. The definition of toxin could be greatly improved.
    ii. For example, ISO35001 uses "substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants. This includes substances and materials, natural or as a result of biotechnology, that may contain toxins, any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance."
        1. The definition should not include proteins or peptides whose primary adverse effect results from allergic or hypersensitivity responses (e.g., sensitizers).
        2. Later in the Policy, when defining the Category of research, would be the appropriate time to limit the scope of which toxins fall under the Policy (e.g., Research with protein or peptide toxins not on the Select Agent list and with an LD50 of less than 100 micrograms per kg body weight.)

e. **Section IV-1 (Research that Requires NIH and IBC Approval Before Initiation): *Research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL.***
    i. Emerging and zoonotic agents:
        1. For those whose research focuses on the identification of new biological agents, the Policy offers no regulatory path to work with these agents. Once identified as an emerging or zoonotic agent with no risk group or biosafety level recommended in the BMBL, the research must be approved by NIH. However, without the ability to work with the agent, the researcher cannot generate the data required for NIH to conduct the risk assessment.
        2. Without the ability to perform this research, US researchers will stop performing this work. It will then fall to international researchers to spearhead this work, leaving US researchers lagging behind.

3. **We recommend** that a clear approval pathway is described in the Policy to allow researchers to generate the data required for a risk assessment. This would best be performed by the local IBC.

ii. Novel agents:
   1. The definition of novel agents includes chimeras. Many researchers generate chimeras (especially within a family of viruses) to study the basic biology of these agents; in these cases, the representative family member or the parental agents often already have risk groups assigned or biosafety levels recommended. Research with such biological agents does not qualify as "higher risk research" requiring NIH approval; indeed, these experiments currently fall within Section III-D of the *NIH Guidelines*, clearly demonstrating that for decades NIH has determined that the work can be reviewed by the local IBC and does not require NIH approval.
   2. **We recommend** that research involving chimeric agents generated within the same family (for viruses) or the same genus (for bacteria or fungi), may be reviewed by the IBC.
   3. **We recommend** that research involving chimeric agents where the natural sources have risk groups assigned and/or biosafety levels recommended, may be reviewed by the IBC.

f. **Section IV-2 (Research That Requires IBC Review and Approval Before Initiation)**
   i. This section states "For initial submissions of research within the scope of the policy, and not otherwise specified in other sections, review and approval must be obtained from the IBC before initiation."
   ii. Since the Policy includes a regulatory catch-all ("not otherwise specified in other sections"), the Policy must include a section that clearly delineates research that is outside the scope of the Policy. Institutions cannot rely on one-off notes to define research that is outside the scope (e.g., "[Note: Experiments involving RG1 wild-type biological agents are not subject to this Policy]"). Without clear delineation, entities will vary widely between unintentional noncompliance and overly requiring IBC review and approval for work that is outside the scope of the policy.

g. **Section IV-2: *Research involving RG3 or RG4 wild-type biological agents.***
   i. We have no objection to including RG3 and RG4 biological agents within scope of the Policy, as our institution already requires that work with these agents be approved by the local IBC.

h. **Section IV-2: *Research involving genetically modified cells, viruses, or organisms, other than plants (e.g., certain vectors, replicons, gene drive modified biological agents, GDMOs).***

i. Policy must be well written and clear; this category is a clear example of policy that is not well written. It is misplaced within the tiers of review; contains terms that are either not defined or badly defined; and conflicts with other categories of research within the Policy. Entities will be uncertain how to comply with this category, leading to chilling effects on the research community, additional administrative burden, and unintentional failures to comply with the Policy.
ii. This category is misplaced within the tiers of review. Research with genetically modified cells should be at most within Section IV-3 (delegate review), if not Exempted completely.
    1. The *NIH Guidelines* has included an exemption for recombinant DNA molecules containing less than one-half of any eukaryotic viral genome that are propagated and maintained in tissue culture at least since the Federal Register Notice in 1994 (Effective June 24, 1994, Published in Federal Register, July 5, 1994 (59 FR 34472)). The NIH Director has therefore determined that such experiments do not present a significant risk to health or the environment. The Policy does not describe how the inclusion of such research in the Policy will increase biosafety and biosecurity. In addition, while a single researcher registering for this work would not be a significant burden, the total number of registrations will constitute a significant collective administrative burden on the IBC and researchers that is not commensurate with the very low biosafety risk.
    2. Genetic modification of cells is of very low biosafety risk (barring some introduction of nucleic acids from certain biological agents, like RG3 or RG4 agents, or that will generate toxins). Such work should be exempt from the Policy.
iii. Genetic modification is defined by the Policy, but in such an expansive way that it is prohibitive to research.
    1. As an example: as written, the Policy no longer considers administration of recombinant nucleic acids (e.g., RNA vaccines) in humans to be within scope, compared to the *NIH Guidelines*, where it is within scope (Section III-C-1). However, the Policy includes “genetic modification” of cells and organisms, which as defined includes introduction of nucleic acid molecules that can be transcribed or translated (e.g., RNA vaccines). The Policy does not describe how it has conducted a risk assessment in which deliberate administration of an RNA vaccine into a human is not within scope, yet transfection of the RNA vaccine into cell culture or administration into an animal is within scope and requires IBC approval.
iv. Organism is not defined by the Policy, which makes this category frustrating to understand and will lead to significant unintentional noncompliance.

1. As written, this category appears to include animals, despite the category of “transgenic organisms at BSL1/ABSL1” listed in Section IV-3.
2. The word organisms must be defined by the policy or replaced in this section.

v. Vector is not defined by the Policy, which will lead to significant unintentional noncompliance. Is the intention here to regulate viral vectors (e.g., lentiviral), arthropod disease vectors (e.g., mosquitoes), or something else?

vi. Gene drive modified biological agents is not defined and is a confusing term. Biological agents in the Policy are defined as bacteria, viruses, fungi, or parasites, yet gene drive technology requires Mendelian genetics, such that this would be limited to fungi or parasites. The subsequent use of GDMO in this category suggests that gene drive modified biological agents are different from GDMOs, but this delineation is not clear.

vii. GDMOs are not defined in the Policy.

viii. **We recommend** that this category be removed from the Policy or extensively re-written, as described below.

1. The definition for Genetic Modification should be re-written to be limited to stable alterations in the genome. Definitions for organism, vector, GDMO and gene drive modified biological agents must be added to the Policy (or removed).
2. Research with genetically modified risk group 3 and 4 biological agents should be approved by the IBC. Research with genetically modified risk group 2 biological agents should be approved by IBC delegate.
3. Research with GMDOs should be approved by the IBC.
4. Review and approval of research with genetically modified cells should be dependent on the modification, some of which may fall within IBC approval, delegate approval, or be completely exempt from the Policy.

i. **Section IV-2:** ***Research with primary cells that may be contaminated by adventitious agents.***

i. As noted above, the Policy does not define adventitious agents. Therefore, entities will be uncertain how to comply with this regulation and will rapidly be in noncompliance.

ii. If the intention of the Policy is to regulate primary cells that may be contaminated by bloodborne pathogens, there is a significant risk assessment issue: research with samples that may be contaminated requires full IBC review, yet research with known RG2 biological agents requires delegate review.

iii. For clinical samples suspected to contain higher consequence pathogens (*Brucella*, Herpes B, *M. tuberculosis*, etc.), the BMBL states that BSL2 practices, containment equipment, and facilities are recommended for routine

handing of clinical specimens of human or animal origin. The Policy should harmonize the level of review required for these samples: at most they should require delegate review.

1. **We recommend** that this section be removed from the Policy.
2. **If it must be regulated by the Policy,** "adventitious agent" must be clearly defined within the Policy.
3. **If it must be regulated by this Policy, we recommend** that this work not require IBC or delegate approval as long as the entity is complying with OSHA Bloodborne Pathogens Standard or its equivalent.
4. **If it must be regulated by this Policy, we recommend** that it should not fall under the category of requiring IBC approval and should at most be in Section IV-3, where delegated review is permitted.

iv. If the intention of the Policy is to regulate primary cells that may be contaminated by any unknown biohazard (for example field samples), that is not clear and needs to be much more clearly defined.

j. **Section IV-2: *Research with wild type or genetically modified RG2 biological agents for which lower containment is requested, or research with wild type or genetically modified RG3 or RG4 biological agents that NIH has previously approved to be conducted at lower containment.***

i. The Policy implies that there will be a workflow of (1) an entity submits an initial request for NIH to lower containment involving wild type or genetically modified RG3 or RG4 biological agents, (2) NIH will make a determination on whether that lower containment is appropriate, (3) NIH will be responsible for publishing approved determinations of appropriate lower containment for these agents, (4) subsequently, research involving these agents may be approved by the IBC alone (without NIH approval).

1. This workflow should be expressly stated in the Policy to minimize confusion. This includes a clear statement that once NIH has made the determination and published it, other entities will not be required to obtain NIH approval. This would be in contrast to the current system, where approvals are provided only to the single PI at the single institution.
2. The method by which NIH will publish these determinations should be described, including the minimum time frame (determinations will be published within 1 month, within 6 months, annually, etc.).
3. The Policy should be clear on how much information will be released together with these determinations. Specifically, whether the information includes security sensitive information or unpublished data.

k. **Section IV-3 (Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members): *Research involving RG2 wild type biological agents.***

i. We have no objection to including RG2 biological agents within scope of the Policy, as our institution already requires that work with these agents be approved by the local IBC.
ii. However, we are very concerned that there is not a thorough list of RG2 biological agents and/or biological agents that are recommended to be worked with at BSL2. Will all agents not listed in the BMBL require review by NIH?
iii. **We recommend** that the NIH make a detailed, publicly available list of RG1, RG2, RG3, and RG4 biological agents to supplement the BMBL. Appendix B of the *NIH Guidelines* should serve as the backbone of this document.
    1. The inclusion of RG1 organisms is an important part of such a list, since they are outside the scope of the Policy, yet the Policy specifically states that "absence of agent specification in the list of RG2-RG4 does not imply automatic or implicit classification as RG1".
    2. If other federal entities (USDA, CDC, etc.) participated in creating a central list that also includes plant or agricultural considerations, that would be greatly appreciated.
iv. If NIH cannot make a detailed publicly available list of RG1, RG2, RG3, and RG4 biological agents to supplement the BMBL, **we recommend** that the Policy clearly states that the local IBC has the authority to perform the risk assessment and make that determination.

l. **Section IV-3: *Research conducted with transgenic organisms at BSL-1/ABSL-1.***
    i. The purchase and transfer of transgenic rodents requiring BL1 containment is exempt in the NIH Guidelines (Appendix C-VII). Further, the generation of certain BL1 transgenic rodents is exempt in the NIH Guidelines (Appendix C-VIII). In 2011, NIH deemed that "… these breeding experiments do not pose an appreciable risk to human health or to the environment. In addition, while registration with the IBC is not a significant burden, the total number of registrations required can constitute a significant collective administrative burden on the IBC and researchers that does not appear to be commensurate with the very low biosafety risk." (January 19, 2011, Federal Register, January 19, 2011 (76 FR 3150)). As documented in NIH guidance documents, the subsequent use of these BL1 transgenic rodents is also exempt (https://osp.od.nih.gov/wp-content/uploads/2022/11/Animal_Activities_Table.pdf). The same risk assessment should apply today, and the Policy should not require that work with transgenic rodents that can be housed at ABSL1 be approved by the IBC.
    ii. As noted previously, there is no definition of *organism* in the Policy. Therefore, **we recommend** changing this to *animal* in this section.

iii. We understand that research with some transgenic animals may not have had the time to demonstrate the same safety track record as transgenic rodents and therefore should continue to require IBC approval before that research is conducted. We would recommend that NIH seriously consider that transgenic fruit flies or zebrafish could be exempted due to their safety track record.
iv. **We recommend that this be re-written as:** Research conducted with transgenic animals, other than transgenic rodents, fruit flies, and zebrafish that may be housed at minimum BSL-1/ABSL-1/ACL-1.

m. **Section IV-3: *Research with genetically modified RG1 biological agents.***
   i. Certain research not requiring NIH-OSP approval and not involving DNA from RG3, RG4, or restricted organisms with specific risk group 1 biological agents is exempt in the NIH Guidelines (Appendices C-II, C-III, C-IV, and C-V), having been determined by the NIH Director to not present a significant risk to health or the environment. The Category here (research with genetically modified RG1 biological agents) contradicts this determination and would require that work that was previously exempt now requires IBC approval. The Policy has not described why this risk assessment has changed.
   ii. **We recommend that this category be removed from the Policy.**
   iii. Additionally, a list of RG1 biological agents is not available. If any part of the Policy references RG1 biological agents, including as work that is outside the scope of the Policy, a list should be developed and published by NIH as part of this Policy, or the local IBC should be granted the authority to designate agents as RG1.

n. **Section IV-3: *Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes.***
   i. This category of research is of low biosafety and biosecurity risk. The Policy fails to describe how regulating this research will increase biosafety or biosecurity. This category will set entities up for failure, with no clear benefits to our biosafety programs.
   ii. Registering research with plasmids will lead to extensive unintentional noncompliance. Researchers generate plasmids regularly and the requirement to obtain approval for these plasmids from the IBC will be a severe bottleneck.
   iii. The Policy fails to describe the extent of what is required to be registered as part of this section. Only the plasmid backbone? The backbone with every gene the researcher will insert? The backbone with every gene and every mutation of that gene?
   iv. The administrative burden for researchers and the IBC will be significant and is not balanced by any increase in biological safety.
   v. **We recommend that this category be removed from the Policy.**

o. **Section IV-3: *Research with well-characterized cell lines.***

i. Registering work with well characterized cell lines will lead to extensive unintentional noncompliance. The administrative burden will be crippling for researchers and IBCs. This category will set entities up for failure, with no clear benefits to our biosafety programs.
ii. The Policy fails to describe the biosafety concern that is being addressed by this category of research.
iii. The Policy does not describe the extent of what is required to be registered. It is solely that a researcher is performing work with cell lines? Is it every cell line that the researcher will work with? May the entire ATCC catalogue be approved?
iv. **We recommend that this category be removed from the Policy.**

p. **Section IV-3: *Research with biological toxin proteins not on the Select Agent list*.**
   i. Under the definition within the Policy, this category includes food allergens, animal allergens, even FBS, since they can cause harm to humans, yet there is no indication that this is intended. The milk that a researcher is using as part of a Western blot falls within scope of this category.
      1. There is a conflict between the wording in this Section (research with biological toxin proteins) and the definition in the Policy for Toxin (a protein or peptide produced …). This conflict makes it difficult to understand what is within the scope of the category.
   ii. This category of research must include a clear definition of which toxins are within scope, including an LD_{50}, or entities will be inadvertently noncompliant.
   iii. At our institution, work with toxins are already regulated by our Chemical Safety Committee, which provides regulatory oversight of this work. Additional oversight by the IBC will not increase safety and will instead increase regulatory burden.
   iv. **We recommend that this category be removed from the Policy.**
   v. **If this category is not removed, we recommend that this be re-written as:** Research with biological toxin proteins with an LD_{50} in vertebrates of <100 micrograms per kilograms of body weight.
      1. Additionally, a list of toxins currently classified under this category must be provided in the Policy. The list of toxin molecules classified as to LD_{50} that is currently available from NIH OSP under the *NIH Guidelines* (Appendix F-1) should serve as the backbone of this list.

3. **Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).**
    a. **Risk Groups as Hazard Characterizations vs. Site-Specific Risk Assessment**
        i. Risk Groups remain valuable tools for initial hazard communication and agent characterization, but they should not independently dictate containment or review levels. The final policy must preserve site-specific and experiment-specific assessment of agent characteristics, procedures, scale, routes of exposure, personnel expertise, facilities, and available mitigations. This aligns with Section V-E of the draft policy, which explicitly acknowledges that Risk Groups and Biosafety Levels are related but non-equivalent concepts.
    b. **Critique of Mandatory IBC Petitions for Emerging, Novel, or Unlisted Agents (Section III-B)**
        i. The 'IBC Functions' section (fifth bullet) directs the IBC to petition NIH to determine the minimum biocontainment level for emerging, novel, or zoonotic agents 'for which the RG classification or containment level is not available in the BMBL,' prohibiting IBC approval until authorized by NIH and any other applicable entities.
        ii. **Terminology Inconsistency:** The draft text treats 'RG classification' and 'containment level' as alternative terms residing in the BMBL. However, Section V-E correctly states that RGs and BSLs are non-equivalent. NIH must use these terms consistently across all policy sections.
        iii. **BMBL Functionality & Misconception:** The Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual does not assign Risk Groups; it provides Agent Summary Statements with recommended Biosafety Levels. A regulatory condition referring to an RG classification 'in the BMBL' cannot be fulfilled.
    c. **Jurisdictional Ambiguity:** The phrase 'and any other applicable Federal, State, or local entities' introduces immense ambiguity. NIH must explicitly identify these entities, specify whether approvals are sequential or concurrent, clarify coordination protocols, and establish resolution pathways when determinations conflict.
    d. **Overbroad Scope & Unintended Petition Backlogs:** As written, the petition requirement could be interpreted as applying to non-pathogenic genetically modified constructs or benign RG1 organisms that are not explicitly named in the BMBL. NIH must explicitly clarify that unlisted, non-pathogenic RG1 agents do not require federal petitioning.
    e. **Reusable Determinations & Response SLAs:** Section III-D commits NIH to publishing determinations for lowering RG3/RG4 containment but omits

determinations for emerging or novel agents. NIH should publish all containment determinations (agent, modification, approved containment, and rationale) in a searchable public database that other institutions may rely upon as established precedent. Furthermore, NIH must set a target response timeline (e.g., 30 calendar days) rather than relying on the subjective term 'timely.'

f. **Definitive Source for Risk Group Assignments**
With Risk Group assignments removed from the former Appendix B and absent from the BMBL, NIH must provide an authoritative, version-controlled federal repository or clear objective criteria for assigning Risk Groups to non-recombinant agents. Without standardized federal classifications, institutions will reach conflicting conclusions for the same agent, compromising national oversight consistency.

g. **Avoid Rigid Containment Prescriptions (GDMOs and Influenza Research)**
Rigid, one-size-fits-all containment rules conflict with performance-based risk assessment. A universal minimum of BSL-2 for Gene Drive Modified Organisms (GDMOs) does not map effectively to specialized containment systems (e.g., Arthropod Containment Level [ACL] guidelines, USDA/NCAR Greenhouse standards, or aquatic facilities). NIH should permit equivalent risk-based containment modalities and issue specialized guidance. Additionally, containment mandates for influenza constructs should specify exact phenotypic traits, host range, and pathogenicity markers rather than sweeping in constructs based on raw genomic segment proportions.

Summary of Requested Regulatory Modifications

Topic Area	Draft Policy Flaw	Requested NIH Modification
Risk Groups vs. BSL	Treats RGs as mandatory containment triggers rather than hazard descriptors.	Explicitly confirm in Section V-E that RGs do not independently dictate BSLs; preserve local risk assessment.
BMBL & Petition Scope	Cites RG lists in BMBL (which do not exist) and lacks scope limits.	Correct BMBL reference; exclude non-pathogenic RG1 agents from mandatory federal petitioning.
Federal Precedents	No commitment to publish determinations for novel/emerging agents.	Publish all containment decisions in a searchable public database with a 30-day target review timeline.
GDMOs & Influenza	Applies universal BSL-2 to GDMOs and rigid segment ratios to Influenza.	Allow specialized containment (ACL, Greenhouse, Aquatic) and calibrate Influenza rules to phenotype.

4. **Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions).**
    a. No comments at this time.

5. **Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.**
    a. Refine the definition of a reportable incident and provide clearer thresholds for reporting to support a risk-based, consistent approach across institutions. Clear thresholds improve consistency and allow NIH to focus regulatory oversight on events with true potential public health or community significance.
    b. **Decouple Regulatory Reporting from Public Website Posting**: Requiring institutions to publicly post unredacted investigative reports and meeting minutes for routine or minor incidents creates severe unintended consequences:
        i. Publicly posted incident reports inadvertently provide sufficient detail to identify involved personnel.
        ii. Publicly linking Principal Investigators, grant numbers, and specific facility locations exposes researchers to harassment, physical threats, and targeted cyber-attacks, particularly in sensitive animal research domains.
        iii. Aggregated public postings reveal institutional research security information. Automated AI scraping tools can harvest these public records to map national high-consequence research capabilities, directly conflicting with federal research security directives and Select Agent regulations.
        iv. Forcing minor, fully mitigated events into public view suppress internal reporting of near-misses and borderline events out of fear of public backlash or reputational damage.
    c. **Resolving Undefined Categories & Technical Definitions**: To eliminate ambiguity, prevent administrative overload, and protect local reporting culture, NIH must establish precise definitions for the following core terms in Section II:
        i. **Incident:** A confirmed theft, loss, or release (such as an occupational exposure or a release outside the defined biocontainment barriers) of biological material under the scope of the Policy.
        i. **Release (Loss of Containment or Occupational exposure):** Release means a failure in biosafety practice and/or equipment such that there is occupational exposure of the person(s) working in the laboratory, and/or escape of the biological material beyond the defined biocontainment boundary.
        ii. **Basic First Aid vs. Agent-Specific Medical Treatment:** NIH must explicitly align medical treatment with OSHA standards (care beyond basic first aid). NIH must clarify that precautionary, non-specific post-exposure prophylactic (PEP) treatment or routine medical consultations do not constitute agent-specific treatment triggering 24-hour federal reporting.
        iii. **Potential Exposure:** Must be defined as an event occurring in the active presence of a biohazard where primary barriers or PPE were breached, creating a credible exposure pathway. Equipment or PPE failures occurring in the absence of active biohazardous agents are not potential exposures.

iv. **Compliance Violation vs. Administrative Non-compliance:** Must distinguish administrative non-compliance (e.g., late paperwork, minor log errors) from substantive biosafety non-compliance (e.g., unapproved research initiation or unauthorized containment lowering). Administrative non-compliance and low-risk items must NEVER necessitate a 24-hour reporting timeframe.
v. **Minor Spill:** Must remove subjective terms like generally and define minor spills.

d. Institutions vary in their meeting structures, recordkeeping practices, information systems, and use of software platforms that may automatically generate meeting records or summaries.
   i. NIH should require the specific content elements needed to support transparency and accountability, such as review category, approval decision, containment level, and required conditions, rather than mandate a rigid template. A content-based approach would allow institutions to use existing processes and technologies while ensuring that required information is consistently documented and made publicly available, subject to appropriate protections for sensitive information. NIH should also provide flexibility in the documentation format of public meeting minutes and incident reports.

6. **Feedback on the implementation resources and areas in which additional guidance would be beneficial.**
    a. **Provide risk assessment guidance for self-aggregating proteins (**Policy Sections II and V-A). The definition already limits prions and self-aggregating proteins to misfolded forms that self-propagate and cause neurodegenerative disease. Provide practical examples and risk assessment guidance for applying that definition, including how to distinguish in-scope materials from ordinary physiological protein aggregation.
    b. **Clarify oversight of computational and AI assisted work (**Policy Sections II and V-C). Clarify whether purely computational design of a novel biological agent, without synthesis or experimental manipulation, falls within the Policy's definition of laboratory research. Distinguish this question from risk assessment of physical agents designed with computational or AI tools. Provide practical guidance on evaluating the resulting biological hazards and identifying when additional expertise is needed.
    c. **Provide a minimum 24-month phased implementation period** The proposed six-month effective date is not realistic for institutions that must inventory newly covered research, obtain an approved Biosafety Assurance, revise policies, redesign electronic systems, build public-facing processes, establish redaction standards, revise incident workflows, train affected communities, secure institutional approvals and funding, or in some cases establish an entirely new IBC. NIH should provide at least 24 months after publication of the final policy and complete implementation materials, with phased milestones and provisional or deemed assurance mechanisms that prevent interruption of ongoing research.
    d. **Pilot the policy and templates**: NIH should pilot the assurance, meeting-minutes, incident-reporting, risk-assessment, and delegated-review tools with institutions representing different sizes, missions, research portfolios, and program maturity. Pilot findings should be published and used to refine burden, clarity, and usability before requirements become mandatory.
    e. **Develop implementation resources**: Needed resources include a Biosafety Assurance template; model policies; decision trees; risk-assessment forms and worked examples; training material for IBC members, BSOs, PIs, and staff; sample completed minutes and incident reports; clear redaction guidance; a national Risk Group and containment determination database; and guidance for external, shared, and consortium IBC models.
    f. **Address the cost of compliance:** The policy should not operate as an unfunded mandate. Other regulatory agencies are required to assess financial impact of policy changes, in lieu of this, NIH should consider dedicated biosafety funding supplements, explicit allowability of appropriate biosafety costs in direct or indirect

cost structures, workforce development programs, shared training resources, and implementation support targeted to smaller and less-resourced institutions.

g. **Allow flexible institutional models**: The final policy should expressly permit shared or consortium IBCs, external IBC services, and mutual-aid arrangements. Requirements for unaffiliated members and specialized expertise should be flexible enough to remain workable in small, rural, geographically isolated, or institution-dominated communities while preserving meaningful independent input.

I thank NIH for allowing us the opportunity to provide comments on this Draft Policy. We look forward to seeing a second draft of the Policy and will remain fully engaged in this process.

462. Iwona Spath

I am responding: On behalf of myself

Name: Iwona Spath

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Associate Biosfety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Response-Draft-NIH-Biosafety-Policy-1.pdf

Description: Response -Draft -NIH-Biosafety-Policy

The Draft NIH Biosafety Policy for Research Involving Biohazards (the Policy) is intended to be an update to the existing NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines). However, the result is a policy that presents a confusing mixture of incomplete rules that ignores many key features of the NIH Guidelines that were crafted and refined over decades of consideration and interpretation. The new policy was an attempt to streamline the oversight of the Institutional Biosafety Committee (IBC) and provide more authority. Unfortunately, the ambiguity and lack of examples create greater confusion where little to none had existed.

The Policy shifts the focus of its oversight to human-centric pathogens in a way that ignores the potential negative economic and societal outcomes of pathogens that infect animals and plants. While the Policy states that pathogens infecting animals and plants will be addressed by policies from other agencies, the lack of such policies is very notable and concerning. It is strongly recommended that the Policy reconsider the absence of animal and plant pathogens that do not infect humans to ensure appropriate and consistent oversight is provided.

The Policy sets forth an extremely aggressive timeline for implementation and compliance. Institutions will have six months from Policy publication to implement all changes. The Policy fails to provide a framework for how ongoing basic sciences research and clinical research that is subject to the NIH Guidelines will be impacted. For example: will review/approval of research by the IBC be halted pending acceptance of the institutions AOR assurance by the NIH? Moreover, guidance will necessarily change for how institutions will handle HGT studies (which are not directly referenced or redefined in the Policy) and how IBCs are expected to work with the local Institutional Review Board (IRB)

Compliance with this policy will require changes in institutional policy, training materials, printed materials, and significant changes to oversight systems. Electronic systems that are employed to ensure compliance with applicable federal policies are often managed and updated by third-party companies. Institutions will be dependent on the speed with which these companies will be able to complete the necessary changes. Making changes will also be dependent upon accurate interpretation of the Policy, which will likely not be settled by the time it is published. The time and financial costs of making such changes will be significant.

The Policy is also being implemented within a similar timeframe as the United States Government Policy for Stopping High-Risk Life Sciences Research (DGOF Policy). There is a high degree of overlap between these policies but nuanced differences will make implementation of both policies at the same time an incredibly difficult burden on both research professionals and administrative staff. Moreover, the Policy states that institutions must demonstrate compliance within 6 months of implementation but no description of how compliance will be demonstrated.

There are noted gaps within the definitions provided within the Policy that are cause for concern. In particular, the definition of Biological Agent focuses on agents that cause disease in healthy individuals. This definition does not account for microorganisms that are commensal in humans but may exacerbate health conditions if exposure occurs. Agents that cause disease in humans are worth studying, and therefore providing oversight, due to their potential to cause disease in humans if certain conditions are met or fortuitous genetic modifications naturally occur. This definition also does not encompass agents that do not cause disease in humans but enhance the pathogenicity of the bacteria they infect, e.g., phages.

The focus on agents that cause disease in humans is also concerning because the ecosystem is broad and includes animals. Biological agents that are infectious to animals or plants but not humans could have significant societal and economic impacts. Absent guidance from other, relevant agencies, it is unclear how oversight will be provided to these agents.

The definition of toxin is also ambiguous as it does not describe what is meant by harm to a human. Some small proteins, such as allergens, are not toxic but are still capable of causing acute harm or harm following long-term exposure. Overall, the definitions need to be more descriptive and less available for interpretation.

Similar to the definitions section, the roles and responsibilities section, Section III, would greatly benefit from more precise and descriptive language as well as examples of how to implement this policy. Examples should be provided for biosafety assurance, posting minutes, reporting and posting incidents, and specific training requirements. The requirement for a Biosafety Officer (BSO) is also unclear: some sections state that it is required for research at BSL3 and higher while other sections state that a BSO is required for research with organisms that are Risk Group (RG) 3 and higher. These statements are incongruous and conflate Risk Group with Biocontainment Level. Moreover, many responsibilities are assigned to the BSO throughout this policy despite the fact that the position is not formally required in most instances when such work will be conducted (at BSL2 and below). Additional guidance regarding what responsibilities the BSO may delegate and to whom would also be helpful.

This section also states that the NIH must be petitioned to determine the appropriate biocontainment level or reduce the biocontainment level for RG3 and RG4 organisms *each time* a request is made. Lentiviral vectors are ubiquitous in life sciences research despite the parent organism earning a RG3 rating. Nevertheless, these agents are typically handled at BSL2. Will the NIH be providing a blanket downgrading of these agents to BSL2? Will such a request be granted at an institution level? Or would downgrading such organisms require a different request dependent upon transgene?

The role and responsibilities of the Principal Investigator (PI) are also outlined in this section but would benefit from additional clarity. This section states that the PI must initiate the risk assessment process. Guidance for how this should be documented would support this process. The PI is required to submit amendments when biorisk

changes but this section does not provide guidance for how the alteration (or increase) in risk is determined. Lastly, additional guidance regarding the PI's responsibility to submit voluntary safety/near miss information would be appreciated and if this information should be relayed through the BSO and/or the IBC and/or another institutional official.

This section should also provide guidance about how the NIH will assign containment levels for both novel and existing biological agents. There is some information about this process, however, it is buried in four short bullet points at the end of the document and provides insufficient guidance. Additional guidance should also be provided regarding so-called "low" or "high" risk activities. These qualifiers for risk are relative and cannot be consistently applied. Administrative and engineering controls are intended to reduce risk before a researcher even begins work. Thus, risk is inherently lower with well-trained staff and well-appointed facilities. Moreover, some research institutions are more risk-tolerant than others.

The Policy should also consider bringing forward major tenants of the NIH Guidelines that continue to be relevant. For example, the Policy no longer explicitly prohibits cloning of clinically relevant drug selection markers into human pathogens. While this activity would likely be prohibited or heavily regulated by the DGOF Policy, that policy is not directly referenced and should be. Moreover, the structure of the NIH Guidelines that clearly defines categories of research and the approval required for each should be considered for the Policy. These categories for research provide concrete examples for researchers when determining the type of research they are conducting and guidance for biosafety professionals and IBCs when reviewing and approving such research.

While it can be generally agreed upon by biosafety professionals that the NIH Guidelines needed to be reconsidered, one major benefit to the aged document is the iterative process of defining and redefining research categories. This process has occurred throughout the lifetime of the document and is thanks to diligent, considerate, and critical researchers and biosafety professionals. In contrast, this Policy significantly lacks the clarity of research categories that the current NIH Guidelines provides. Each section of research that is covered in Section IV of this document needs to provide concrete examples of the categories to ensure appropriate and consistent application. Consistency of application is of critical importance to ensure overall compliance and reduce confusion among research staff and research programs writ large.

463. The George Washington University

I am responding: On behalf of an organization

Name:

Name of Organization: The George Washington University

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comments-on-NIH-Biosafety-Policy-NOT-OD-26-112.pdf

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

Office of the Vice Provost for Research

October 19, 2026

National Institutes of Health
Office of Science Policy
6705 Rockledge Drive
Bethesda, MD 20892

Re: Request for Comment on Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear NIH Office of Science Policy:

The George Washington University (GW) appreciates the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. As a leading research university with a strong commitment to biosafety, regulatory compliance, and the responsible and ethical conduct of research, GW supports efforts to modernize biosafety oversight and establish a comprehensive framework that reflects the evolving nature of biological research.

GW shares the concerns expressed by ABSA International (the Association for Biosafety and Biosecurity) in their comments submitted to NIH's Office of Science Policy. ABSA International represents the nation's leading biosafety professionals and provides critical expertise regarding the practical implementation of biosafety policies within research institutions. We urge NIH to carefully consider and incorporate ABSA's recommendations as it develops the final policy.

While GW supports the overarching goals of strengthening biosafety and promoting transparency, we have several concerns regarding specific provisions of the draft policy. Informed by the expertise of GW investigators, research safety administrators, and regulatory committee members, we offer the following additional comments on the proposed NIH policy.

IBC Approval Periods
GW is concerned by the proposed requirement that Institutional Biosafety Committee (IBC) approvals be granted for periods not to exceed three years, requiring a de novo review and submission at the end of each cycle. The current five-year approval framework has supported effective oversight while allowing our institution to focus resources on risk assessment, compliance monitoring, laboratory inspections, protocol amendments, and investigator engagement.

Reducing the approval period to three years would substantially increase administrative burden for the institution, investigators, and the IBC without a demonstrated corresponding improvement in biosafety outcomes. The proposed change would require the review and resubmission of many protocols that have undergone no significant changes in risk profile, diverting institutional resources from important oversight activities. GW encourages NIH to retain the existing five-year approval cycle or evaluate a tiered approach that considers a project's risk and complexity.

Incident Reporting and Public Posting Requirements
GW supports robust incident reporting systems and recognizes the value of transparency in strengthening biosafety practices. However, several aspects of the proposed reporting and public disclosure requirements may create unintended consequences that could undermine a strong culture of safety.

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The draft policy would require extensive public posting of incident reports, IBC meeting materials, and compliance-related information while also creating new reporting expectations for compliance deviations and other biosafety events. Institutions thrive when investigators and laboratory personnel feel empowered to promptly report mistakes, near misses, and possible noncompliance so that corrective actions can be taken and lessons can be shared.

The combination of expanded reporting obligations, public disclosure requirements, and potential enforcement implications may discourage voluntary self-reporting and create a more punitive perception of biosafety oversight. We encourage NIH to carefully evaluate how these provisions may affect institutional reporting behaviors and to ensure that the final policy continues to incentivize the prompt identification and correction of biosafety concerns.

In particular, GW recommends that NIH provide additional clarity regarding the distinction between mandatory reporting requirements and voluntary submissions to the proposed National Biosafety Data and Safety Analysis Center (NBDSAC), including how submitted information will be protected, de-identified, secured, and used.

Additional Clarifications

GW also encourages NIH to provide greater clarity regarding the interaction of this policy with oversight conducted by other federal agencies, the scope of federal review requirements for higher-risk research, and the application of the policy to activities involving non-protein biological toxins and other biohazards that are not fully captured by the current definitions.

GW appreciates NIH's engagement with the research community throughout this process and supports the agency's goal of creating a modern, risk-based biosafety framework. We urge NIH to work closely with institutions, biosafety professionals, and stakeholder organizations such as ABSA International to ensure that the final policy enhances biosafety while remaining practical and sustainable for the research enterprise.

Yours sincerely,



Evangeline J. Downie, Ph.D.
Interim Vice President for Research

464. William Peairs

I am responding: On behalf of myself

Name: William Peairs

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I am submitting these comments in my personal capacity as a biosafety professional. The views expressed are my own and do not represent my employer or any Institutional Biosafety Committee on which I serve. This statement applies to the entire submission.

I appreciate NIH's effort to address biosafety across biomedical research. Broader coverage can help institutions consider hazards beyond recombinant and synthetic nucleic acids. To apply that coverage consistently, institutions need clear criteria for deciding which activities fall within the policy.

Scope

Please explain how the threshold of known or potential risk to human health limits the listed material categories. Applying that threshold to routine research can be less straightforward than identifying the hazards of work involving a known pathogen.

Consider an experiment introducing a low-risk reporter into a well-characterized cell line by electroporation or nucleofection, without an infectious delivery vector. The absence of a viral vector does not resolve every hazard question, but it makes the basis for identifying human-health risk important.

Would this activity be covered because the cells are genetically modified, or must there also be an identifiable basis for known or potential harm? What information supports that determination? Such work can reasonably fall within an institution's biosafety program, but that does not resolve whether federal review requirements apply. Without a clear rule, equivalent work could be excluded at one institution and require approval at another.

Definitions and review categories

Please explain which characteristics distinguish primary materials from well-characterized cell lines for oversight purposes. Compare recently collected human cells, primary cells expanded in culture, and an established line carrying a low-risk reporter. Which facts change applicability, review route, or precautions? These are separate decisions, and a designation such as “established” may not answer all three.

Guidance should explain how to make these decisions when infectious status is uncertain. A sample known to contain HCV presents an identifiable agent-specific hazard. Cells from an apparently healthy donor, or an established line without relevant testing, present different questions about possible adventitious agents. What information is sufficient, and when is additional characterization or testing expected?

My primary concern is the feasibility of making sound decisions in the face of uncertainty, rather than whether the requirements err on the side of caution or permissiveness. If additional testing or characterization is expected, please make clear when and why, and what information is sufficient to reach a decision.

Please also provide practical criteria for applying the definitions of genetic modification and disease-causing self-propagating proteins. For proteins, the definition identifies a hazardous property, but institutions need to know how to evaluate preparations whose capacity for self-propagation or disease is uncertain. Routine protein expression should not require a speculative assessment of whether every expressed sequence could produce a hazardous misfolded protein. Examples and practical screening criteria would help identify preparations warranting closer review.

Gaps in oversight

Researchers have different levels of biosafety expertise and differing risk tolerance. They may describe work as harmless because hazards are low, protective measures are effective, or relevant risks are unfamiliar. Those explanations have different implications.

Please permit institutions to apply defined screening criteria and escalate consequential uncertainty, rather than rely solely on investigator self-classification. Routine activities should not each require a separate formal determination merely to establish that they are outside scope.

Other federal oversight

Please reconcile the provision allowing research to proceed under another federal agency’s oversight with the clinical-review requirements. Specify which NIH-policy obligations remain after the other agency’s applicable approvals or clearances have been obtained.

My concern here is clarity about the requirement itself. As written, I cannot confidently determine what remains required, and I would greatly appreciate an explicit explanation. A worked clinical example would be particularly helpful.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I welcome the use of different review tiers. A simpler route for lower-risk work can direct more attention toward activities with greater uncertainty or consequences. The assessment and documentation requirements should preserve that benefit throughout the process.

Proportionate assessment

Please state expressly that a comprehensive assessment considers all relevant hazards, with the depth of analysis and documentation appropriate to the work. A complete assessment of a simple activity may be brief, even when another activity in the same review tier requires substantial analysis. Examples should demonstrate sufficient assessment without equating thoroughness with document length.

Administrative updates and minimal risk activities

Section III-B links amendment approval to changes that may affect the original biosafety assessment. Please confirm that authorized staff may record updates without that effect, such as a change in an administrative contact, without delegated scientific approval.

I also recommend a screening or registration pathway for defined minimal-risk activities without individual IBC approval. Institutions should establish criteria and responsible personnel, with reconsideration when relevant facts change. Delegation alone can save committee time while leaving most staff work intact or increasing administrative requirements.

Established controls

Please expressly permit assessments to incorporate approved institutional procedures by reference. The record should identify the work, explain why the controls apply, and describe departures or additional precautions. Project-specific factors and decisions should receive the emphasis.

Explicit permission would help institutions confidently use this approach rather than reproduce standard procedures in every assessment.

Incident reporting and disclosure

These are my greatest concerns. Effective accountability depends on reliable information and prompt, candid reporting. I am concerned that requiring full investigations and public reports for covered minor incidents and isolated administrative errors could make the process appear punitive, discourage reporting and cooperation, and erode the trust that a strong safety culture requires. The policy should establish when a full investigation is warranted and when a simpler review and response are sufficient.

Requirements should distinguish administrative noncompliance from exposures or releases with material safety consequences. The required investigation, documentation, and corrective action should reflect the event's significance. Repeated lapses, uncertain controls, or unreviewed changes warrant closer attention, but an isolated administrative lapse should not automatically require the same response as a

serious containment failure.

Please separate detailed oversight records from public accounts. Significant events should receive timely public summaries explaining what happened, actual or potential consequences, the response, corrective actions, and follow-up. Defined minor events should be eligible for concise or grouped accounts, with fuller records retained for oversight and inspection.

OSHA's distinction between detailed injury records and its Form 300A workplace summary offers a useful design analogy. The aim is meaningful accountability with appropriate protection for affected people. If detailed public reports remain required, specify proportionate content for different event categories and protect against identification through combined details.

3. Continued utility of Risk Groups: Risk Groups provide a useful starting point for understanding agent hazards, while Biosafety Levels describe precautions for particular activities. Preserving that distinction supports sound assessment without requiring institutions to assign an agent classification to every biological material.

Please address a common situation: mice are administered human cells, no specific infectious agent is known to be present, and bloodborne-pathogen precautions are used because infectious status is uncertain. A qualified reviewer subsequently evaluates documented characterization or testing that supports reduced precautions for the material.

Would selecting lower containment for subsequent animal housing require full-committee review under the provisions for lowering containment of RG2 agents, even though the initial precautions address uncertain infectious status rather than an identified agent, or could the decision receive delegated review? Would the answer differ if the housing conditions were established during the original approval rather than proposed later as an amendment?

The initial precautions address possible contamination; they do not establish that an RG2 agent is present. Conversely, negative test results do not establish absence of every possible pathogen or automatically justify lower animal containment. Please explain what evidence and documentation are sufficient to make this decision, while preserving professional judgment about relevant testing and remaining uncertainty.

OSHA's June 21, 1994 interpretation recognizes documented characterization of certain human cell cultures when determining Bloodborne Pathogens Standard coverage. Please explain how such evidence may inform the separate NIH assessment, without treating an occupational-safety determination as an automatic animal-containment decision.

A worked example should identify the appropriate review route and when full-committee or federal approval is required. Clear guidance would support consistent decisions without creating a universal testing panel or assigning a Risk Group solely because precautions were initially used.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Making practical biosafety resources available beyond NIH-

funded institutions is a useful part of this effort. Accessible training, technical consultation, assessment tools, and worked examples could provide clear benefits to organizations choosing to participate voluntarily.

I encourage NIH to develop these resources with their intended users and support staged adoption of useful practices. A voluntary incident-learning system could also help institutions share lessons and prevent recurrence. I would welcome a resource comparable to NIOSH, focused specifically on biosafety lessons and prevention (my impression is that's the plan, so I wish you the best of luck!).

Clear explanations of how confidentiality and de-identification operate, and how voluntary submissions are distinguished from mandatory reports, would help contributors understand the protections and responsibilities involved. Straightforward participation and visible benefits would support continued engagement.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Standard templates can improve consistency and make oversight easier to understand. Their instructions should show how sufficient information varies with the event or review and permit equivalent documents generated from existing systems.

Incident reporting

Please distinguish the information expected for initial notification, the completed investigation, and public accountability. Those purposes may require different levels of detail. Building on the template's distinction between initial and final reports, please specify what belongs in each stage and what must be included in the public account.

Requiring the same detailed account for different purposes can create unnecessary disclosure and administrative work without improving the information available for oversight.

Please provide completed examples for an administrative approval lapse, a minor event reviewed locally, and a serious exposure or release. Allowing "not applicable" is helpful, but institutions also need examples of sufficient analysis.

The current template does not appear well suited to administrative matters. For an overlooked renewal, what would constitute a sufficient root-cause analysis and corrective-action response? A completed example should demonstrate the expected depth of explanation and when a brief account is adequate. This would support useful corrective action without encouraging lengthy narratives that add little understanding.

Lower risk events and duplicate public records

The paragraph requiring local review of lower-risk events does not specify use of the incident template, while the later posting provision appears to require it broadly. The full template does not appear well suited to many of these events. Please clarify whether a full investigation and separate template-based public report are required for lower-risk events, and explain what information is actually needed.

I recommend allowing a concise account in publicly posted minutes to satisfy the public-record requirement for defined lower-risk events, without a separate full-template report. Specify the necessary information, including the event's significance, the IBC's review, the response, and preventive action. This would preserve accountability while avoiding duplicate public documents describing the same review.

Please also permit periodic grouped summaries, such as quarterly summaries, for defined recurring minor events where individual narratives add little information. These could complement the minutes, using a summary approach analogous to OSHA Form 300A. Detailed institutional records should remain available for oversight and inspection, with the same privacy protections applied regardless of the public format.

Privacy and unpublished information

I appreciate the permission to protect private and proprietary information. However, details already available elsewhere can identify an affected employee when combined with an incident narrative. A PI's identity, project description, role, date, and medical information may together reveal who was involved.

Please permit omission or generalization when the combination creates a meaningful identification risk, even if individual details are otherwise public. Instructions should reconcile this protection with restrictions on redacting publicly available information.

The person investigating an incident cannot reasonably be expected to know which details of every construct used by a laboratory have been published. A published paper may describe a vector system while the particular construct, modification, or application involved in the incident remains unpublished. This creates a practical risk of inadvertently exposing intellectual property when preparing a public report. Public availability of related research should not be treated as establishing that every experimental detail is public.

Please distinguish information necessary for biosafety oversight from information necessary for public understanding, and allow sufficient time for investigator and appropriate institutional review before publication. Significant events should have useful public summaries explaining consequences, response, corrective actions, and follow-up while protecting unnecessary identifying or proprietary details.

Meeting minutes and publication timing

I support a firm deadline for approving and posting minutes. However, tying approval to the next convened meeting makes the available preparation and verification time depend on the committee's meeting schedule. This is particularly consequential for institutions with frequent IBC meetings.

I recommend an outer deadline of 90 days after the meeting for approval and public posting, with prompt publication once approval and permitted redactions are complete. This would preserve a definite, enforceable deadline while allowing reasonable time to verify an accurate record. Essential

safety decisions, conditions, and corrective actions should be communicated and implemented without waiting for minutes to be finalized.

Please illustrate sufficient minutes for a routine delegated approval, a complex committee review, and a locally reviewed incident. Show how minutes can reference established controls while recording project-specific reasoning and conditions.

Equivalent formats

Please expressly allow electronically generated documents preserving all required information, clear labels, and readability, without requiring the supplied file or table layout. Re-entering information into a separate document creates transcription risks and makes consistent records harder to maintain.

OSHA's acceptance of equivalent recordkeeping forms offers a useful precedent for defining required content while allowing different production methods. Comparable flexibility would support accurate, accessible reports and minutes.

6. Other feedback relevant to this resource: I appreciate NIH's recognition that implementation resources will be needed. Speaking for myself, I want to make this transition successful, and I believe that aim is widely shared among biosafety professionals. The staff revising policies, configuring systems, and training users must also maintain current oversight. Transition work requires staff time before any efficiencies from the new framework become available.

The extent of the proposed changes makes adequate time, clear expectations, and practical guidance particularly important to a successful transition.

Phased implementation

Please establish phased deadlines with distinct milestones for assurances, new submissions, existing approvals, reporting, and public posting. The transition period should begin after essential final guidance, templates, and assurance instructions are available. Allow supported pilot testing before requiring institution-wide implementation.

Publishing these materials with a defined schedule would let institutions organize staffing, systems, and training around stable requirements. Rushed or repeated conversion work can divert experienced staff from the ongoing oversight the policy is intended to strengthen.

Existing assessments and approvals

I am proud of the rigorous risk assessments and sound biosafety decisions made by the committees I work with. I want the transition process to preserve that work while addressing the new requirements.

Please provide an explicit process for carrying forward valid experimental descriptions, hazard assessments, and control decisions. Institutions should be able to map existing research to the new review route, assess newly applicable requirements, and update missing information without

reconstructing prior work.

Please allow previously approved research to transition at its next scheduled renewal, unless a material change or newly identified risk warrants earlier review. With a defined final conversion deadline, institutions could bring existing approvals into the new framework over one renewal cycle rather than reassess all ongoing work at once. Separate instructions should address newly covered research and institution-wide requirements during that period.

The process should specify what may be retained, what requires reconsideration, who may approve the transition, and when fresh review is necessary. Retaining an assessment should not automatically extend approval or waive a newly applicable requirement.

Please also explain the treatment of pending submissions, amendments, and renewals. Provide a continuity mechanism for institutions that submit complete assurances on time and maintain applicable safeguards while awaiting NIH action, so research is not interrupted solely by a processing queue.

Worked examples and continuing guidance

Please publish a substantial, searchable collection of examples covering ordinary cell and vector research, human materials administered to animals, clinical products, purified toxins, administrative updates, renewals, and incidents. Paired examples should identify the facts that change applicability, review route, containment, or reporting.

Include sufficient examples of investigator assessments, independent reviews, delegated decisions, and records incorporating institutional procedures by reference. Explain what investigators must contribute and what qualified biosafety staff may help prepare.

Biosafety Assurance

Getting the Biosafety Assurance right the first time will be an immediate priority for me. The more clearly NIH can describe what a complete and acceptable submission looks like, the better prepared I will be to do my part.

Please provide a submission checklist, a template or annotated outline, completed examples, and the criteria used to assess completeness and approve an assurance. Explain the expected level of detail, what supporting evidence must be submitted, and when links to existing policies and procedures are sufficient.

Please also explain how institutions with multiple IBCs should organize their submissions, how approved transition arrangements should be reflected, how deficiencies will be communicated and corrected, and which changes require an assurance update. Expected review timelines and a clear route for implementation questions would help institutions prepare successfully the first time.

Finally, please provide further public review of material policy revisions and essential implementation

resources before compliance is required.

My highest priority is to do my part in implementing this policy effectively. Clear expectations and practical resources would help me—and others responsible for this work—make the transition accurately, consistently, and with continued attention to protecting people and the environment. I would greatly appreciate any resources NIH can provide to support that effort.

Uploaded File: NIH_Biosafety_Personal_Comments_wmp.pdf

Description: Document is a duplicate of what was put into the boxes, but in PDF form.

Personal Comments on the Draft NIH Biosafety Policy

Response to NOT-OD-26-112
October 19, 2026

1 Scope definitions and gaps in oversight

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I appreciate NIH's effort to address biosafety across biomedical research. Broader coverage can help institutions consider hazards beyond recombinant and synthetic nucleic acids. To apply that coverage consistently, institutions need clear criteria for deciding which activities fall within the policy.

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2 Tiered oversight and calibration to risk

I welcome the use of different review tiers. A simpler route for lower-risk work can direct more attention toward activities with greater uncertainty or consequences. The assessment and documentation requirements should preserve that benefit throughout the process.

Proportionate assessment

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These are my greatest concerns. Effective accountability depends on reliable information and prompt, candid reporting. I am concerned that requiring full investigations and public reports for covered minor incidents and isolated administrative errors could make the process appear punitive, discourage reporting and cooperation, and erode the trust that a strong safety culture requires. The policy should establish when a full investigation is warranted and when a simpler review and response are sufficient.

Requirements should distinguish administrative noncompliance from exposures or releases with material safety consequences. The required investigation, documentation, and corrective action should reflect the event's significance. Repeated lapses, uncertain controls, or unreviewed changes warrant closer attention, but an isolated administrative lapse should not automatically require the same response as a serious containment failure.

Please separate detailed oversight records from public accounts. Significant events should receive timely public summaries explaining what happened, actual or potential consequences, the response, corrective actions, and follow-up. Defined minor events should be eligible for concise or grouped accounts, with fuller records retained for oversight and inspection.

OSHA's distinction between detailed injury records and its Form 300A workplace summary offers a useful design analogy. The aim is meaningful accountability with appropriate protection for affected people. If detailed public reports remain required, specify proportionate content for different event categories and protect against identification through combined details.

3 Risk Groups and Biosafety Levels

Risk Groups provide a useful starting point for understanding agent hazards, while Biosafety Levels describe precautions for particular activities. Preserving that distinction supports sound assessment without requiring institutions to assign an agent classification to every biological material.

Please address a common situation: mice are administered human cells, no specific infectious agent is known to be present, and bloodborne-pathogen precautions are used because infectious status is uncertain. A qualified reviewer subsequently evaluates documented characterization or testing that supports reduced precautions for the material.

Would selecting lower containment for subsequent animal housing require full-committee review under the provisions for lowering containment of RG2 agents, even though the initial precautions address uncertain infectious status rather than an identified agent, or could the decision receive delegated review? Would the answer differ if the housing conditions were established during the original approval rather than proposed later as an amendment?

The initial precautions address possible contamination; they do not establish that an RG2 agent is present. Conversely, negative test results do not establish absence of every possible pathogen or automatically justify lower animal containment. Please explain what evidence and documentation are sufficient to make this decision, while preserving professional judgment about relevant testing and remaining uncertainty.

OSHA's June 21, 1994 interpretation recognizes documented characterization of certain human cell cultures when determining Bloodborne Pathogens Standard coverage. Please explain how such evidence may inform the separate NIH assessment, without treating an occupational-safety determination as an automatic animal-containment decision.

A worked example should identify the appropriate review route and when full-committee or federal approval is required. Clear guidance would support consistent decisions without creating a universal testing panel or assigning a Risk Group solely because precautions were initially used.

4 Voluntary compliance

Making practical biosafety resources available beyond NIH-funded institutions is a useful part of this effort. Accessible training, technical consultation, assessment tools, and worked examples could provide clear benefits to organizations choosing to participate voluntarily.

I encourage NIH to develop these resources with their intended users and support staged adoption of useful practices. A voluntary incident-learning system could also help institutions share lessons and prevent recurrence. I would welcome a resource comparable to NIOSH, focused specifically on biosafety lessons and prevention.

Clear explanations of how confidentiality and de-identification operate, and how voluntary submissions are distinguished from mandatory reports, would help contributors understand the protections and responsibilities involved. Straightforward participation and visible benefits would support continued engagement.

5 Incident reporting and meeting minutes templates

Standard templates can improve consistency and make oversight easier to understand. Their instructions should show how sufficient information varies with the event or review and permit equivalent documents generated from existing systems.

Incident reporting

Please distinguish the information expected for initial notification, the completed investigation, and public accountability. Those purposes may require different levels of detail. Building on the template's distinction between initial and final reports, please specify what belongs in each stage and what must be included in the public account.

Requiring the same detailed account for different purposes can create unnecessary disclosure and administrative work without improving the information available for oversight.

Please provide completed examples for an administrative approval lapse, a minor event reviewed locally, and a serious exposure or release. Allowing "not applicable" is helpful, but institutions also need examples of sufficient analysis.

The current template does not appear well suited to administrative matters. For an overlooked renewal, what would constitute a sufficient root-cause analysis and corrective-action response? A completed example should demonstrate the expected depth of explanation and when a brief account is adequate. This would support useful corrective action without encouraging lengthy narratives that add little understanding.

Lower risk events and duplicate public records

The paragraph requiring local review of lower-risk events does not specify use of the incident template, while the later posting provision appears to require it broadly. The full template does not appear well suited to many of these events. Please clarify whether a full investigation and separate template-based public report are required for lower-risk events, and explain what information is actually needed.

I recommend allowing a concise account in publicly posted minutes to satisfy the public-record requirement for defined lower-risk events, without a separate full-template report. Specify the necessary information, including the event's significance, the IBC's review, the response, and preventive action. This would preserve accountability while avoiding duplicate public documents describing the same review.

Please also permit periodic grouped summaries, such as quarterly summaries, for defined recurring minor events where individual narratives add little information. These could complement the minutes, using a summary approach analogous to OSHA Form 300A. Detailed institutional records should remain available for oversight and inspection, with the same privacy protections applied regardless of the public format.

Privacy and unpublished information

I appreciate the permission to protect private and proprietary information. However, details already available elsewhere can identify an affected employee when combined with an incident narrative. A PI's identity, project description, role, date, and medical information may together reveal who was involved.

Please permit omission or generalization when the combination creates a meaningful identification risk, even if individual details are otherwise public. Instructions should reconcile this protection with restrictions on redacting publicly available information.

The person investigating an incident cannot reasonably be expected to know which details of every construct used by a laboratory have been published. A published paper may describe a vector system while the particular construct, modification, or application involved in the incident remains unpublished. This creates a practical risk of inadvertently exposing intellectual property when preparing a public report. Public availability of related research should not be treated as establishing that every experimental detail is public.

Please distinguish information necessary for biosafety oversight from information necessary for public understanding, and allow sufficient time for investigator and appropriate institutional review before publication. Significant events should have useful public summaries explaining consequences, response, corrective actions, and follow-up while protecting unnecessary identifying or proprietary details.

Meeting minutes and publication timing

I support a firm deadline for approving and posting minutes. However, tying approval to the next convened meeting makes the available preparation and verification time depend on the committee's meeting schedule. This is particularly consequential for institutions with frequent IBC meetings.

I recommend an outer deadline of 90 days after the meeting for approval and public posting, with prompt publication once approval and permitted redactions are complete. This would preserve a definite, enforceable deadline while allowing reasonable time to verify an accurate record. Essential safety decisions, conditions, and corrective actions should be communicated and implemented without waiting for minutes to be finalized.

Please illustrate sufficient minutes for a routine delegated approval, a complex committee review, and a locally reviewed incident. Show how minutes can reference established controls while recording project-specific reasoning and conditions.

Equivalent formats

Please expressly allow electronically generated documents preserving all required information, clear labels, and readability, without requiring the supplied file or table layout. Re-entering information into a separate document creates transcription risks and makes consistent records harder to maintain.

OSHA's acceptance of equivalent recordkeeping forms offers a useful precedent for defining required content while allowing different production methods. Comparable flexibility would support accurate, accessible reports and minutes.

6 Implementation resources and additional guidance

I appreciate NIH's recognition that implementation resources will be needed. Speaking for myself, I want to make this transition successful, and I believe that aim is widely shared among biosafety professionals. The staff revising policies, configuring systems, and training users must also maintain current oversight. Transition work requires staff time before any efficiencies from the new framework become available.

The extent of the proposed changes makes adequate time, clear expectations, and practical guidance particularly important to a successful transition.

Phased implementation

Please establish phased deadlines with distinct milestones for assurances, new submissions, existing approvals, reporting, and public posting. The transition period should begin after essential final guidance, templates, and assurance instructions are available. Allow supported pilot testing before requiring institution-wide implementation.

Publishing these materials with a defined schedule would let institutions organize staffing, systems, and training around stable requirements. Rushed or repeated conversion work can divert experienced staff from the ongoing oversight the policy is intended to strengthen.

Existing assessments and approvals

I am proud of the rigorous risk assessments and sound biosafety decisions made by the committees I work with. I want the transition process to preserve that work while addressing the new requirements.

Please provide an explicit process for carrying forward valid experimental descriptions, hazard assessments, and control decisions. Institutions should be able to map existing research to the new review route, assess newly applicable requirements, and update missing information without reconstructing prior work.

Please allow previously approved research to transition at its next scheduled renewal, unless a material change or newly identified risk warrants earlier review. With a defined final conversion deadline, institutions could bring existing approvals into the new framework over one renewal cycle rather than reassess all ongoing work at once. Separate instructions should address newly covered research and institution-wide requirements during that period.

The process should specify what may be retained, what requires reconsideration, who may approve the transition, and when fresh review is necessary. Retaining an assessment should not automatically extend approval or waive a newly applicable requirement.

Please also explain the treatment of pending submissions, amendments, and renewals. Provide a continuity mechanism for institutions that submit complete assurances on time and maintain applicable safeguards while awaiting NIH action, so research is not interrupted solely by a processing queue.

Worked examples and continuing guidance

Please publish a substantial, searchable collection of examples covering ordinary cell and vector research, human materials administered to animals, clinical products, purified toxins, administrative updates, renewals, and incidents. Paired examples should identify the facts that change applicability, review route, containment, or reporting.

Include sufficient examples of investigator assessments, independent reviews, delegated decisions, and records incorporating institutional procedures by reference. Explain what investigators must contribute and what qualified biosafety staff may help prepare.

Biosafety Assurance

Getting the Biosafety Assurance right the first time will be an immediate priority for me. The more clearly NIH can describe what a complete and acceptable submission looks like, the better prepared I will be to do my part.

Please provide a submission checklist, a template or annotated outline, completed examples, and the criteria used to assess completeness and approve an assurance. Explain the expected level of detail, what supporting evidence must be submitted, and when links to existing policies and procedures are sufficient.

Please also explain how institutions with multiple IBCs should organize their submissions, how approved transition arrangements should be reflected, how deficiencies will be communicated and corrected, and which changes require an assurance update. Expected review timelines and a clear route for implementation questions would help institutions prepare successfully the first time.

Finally, please provide further public review of material policy revisions and essential implementation resources before compliance is required.

My highest priority is to do my part in implementing this policy effectively. Clear expectations and practical resources would help me—and others responsible for this work—make the transition accurately, consistently, and with continued attention to protecting people and the environment. I would greatly appreciate any resources NIH can provide to support that effort.

465. Michael S. Rogers

I am responding: On behalf of myself

Name: Michael S. Rogers

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Work on drug discovery, including for cancer, endometriosis, blindness.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed scope risks encompassing many technologies with long and well-established records of safe use, including replication-deficient lentiviral vectors, routine expression of non-oncogenic transgenes and fluorescent protein fusions, and many common CRISPR-based genome-engineering applications. While appropriate biosafety practices should remain in place, decades of experience suggest that these technologies present fundamentally different risks than novel pathogens, gene drives, or engineered organisms intended for or at risk of environmental release. The final policy should more clearly distinguish mature technologies with extensive safety records from activities that present credible public-health or environmental risks. Failure to do so may substantially expand oversight without corresponding improvements in biosafety.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Oversight should be proportional to demonstrated risk. For laboratories conducting relatively low-risk molecular and cellular research, modernization should ideally decrease administrative burden while improving oversight of genuinely higher-risk activities. Several provisions of the draft appear likely to expand documentation, reporting, and review requirements without a clear demonstration of corresponding safety benefits.

In addition, oversight systems naturally tend toward increasingly conservative interpretations over time. The consequences of under-regulation are highly visible, whereas the costs of excessive regulation are diffuse and rarely measured. Without explicit mechanisms that periodically streamline oversight for mature technologies with strong safety records, administrative burden is likely to grow continuously even when biosafety outcomes do not improve.

I encourage NIH to incorporate objective criteria allowing low-risk, well-established technologies to move into simplified oversight pathways as safety experience accumulates.

3. Continued utility of Risk Groups: Whatever framework NIH adopts, risk assessment should be driven by actual hazard rather than the mere presence of genetic modification. In many cases, genetic modifications substantially reduce risk rather than increase it. A risk assessment system should avoid

creating incentives to treat all genetically modified organisms as inherently higher risk than their parental counterparts. A flexible, evidence-based approach that considers the characteristics of the final agent is preferable to categorical approaches based solely on the use of genetic engineering technologies.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Any mechanisms promoting voluntary compliance should emphasize practical biosafety guidance, training, and dissemination of best practices rather than additional administrative requirements. The strong safety record of U.S. biomedical research is due in large part to professional norms, training, and an established culture of safety. Policies that strengthen those factors are likely to be more effective than policies focused primarily on additional documentation or reporting requirements.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I am concerned by the proposed public disclosure requirements associated with incident reports and meeting minutes. Transparency is important, but transparency should not be confused with public dissemination of detailed operational information. Biosafety discussions often include technical descriptions of containment practices, incident analyses, vulnerabilities, and research procedures.

Excessive disclosure may discourage candid committee deliberations and could provide useful information to individuals or organizations operating outside the strong biosafety culture and accountability systems that characterize leading U.S. research institutions. NIH should consider public summaries of committee actions and incident outcomes rather than requiring disclosure of detailed deliberative material.

6. Other feedback relevant to this resource: The United States has developed a strong biosafety record through a combination of appropriate oversight, extensive training, institutional accountability, and a deeply ingrained culture of safety. As NIH finalizes this policy, it should consider the impact of new requirements on scientific productivity and international competitiveness.

Biomedical research is increasingly global. If low-risk research becomes subject to substantially greater administrative burden without measurable safety gains, innovation may simply shift to jurisdictions with less burdensome oversight. This concern is particularly relevant for rapidly evolving fields such as genome engineering and synthetic biology.

The ultimate goal should be to increase biosafety while reducing unnecessary burden on investigators conducting low-risk research. Success should be measured by demonstrable improvements in biosafety outcomes rather than increases in the number of protocols reviewed, forms completed, or reports generated.

466. ASM

I am responding: On behalf of an organization

Name: Nicole Zimmerman

Name of Organization: ASM

Type of Organization: Professional Organization/Association

Role: Other

Role - Other: Policy Staff

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): microbiology, infectious diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: While understanding that NIH has excluded plant pathogens from the proposed policy because of NIH's focus on human health, ASM members raised concerns that excluding plant pathogen research from NIH oversight could expose the nation's food supply to new risks. ASM requests that NIH work with USDA and other research agencies to ensure oversight over plant pathogen research is sufficient and ensure that the plant pathogen research oversight policies are complementary and not contradictory with oversight of other kinds of pathogen research.

Furthermore, ASM members requested clarification of several of the definitions in the proposed biosafety policy:
• The definition of "toxin" in the policy – "a protein or peptide produced by living organisms that causes harm in humans" -- is broad and could be interpreted to include allergens that humans experience in everyday life, like pollen.
• The policy covers "cells or organisms, other than plants, containing [infectious agents or prions]." However, all higher-level eukaryotic cells contain endogenous retroviruses. ASM members requested clarification that the policy covers cells that are infected whether lytically, latently or persistently.
• The definition of "wild type" and "novel agent or organism" could be subject to differing interpretations of what organisms, cell and viruses are naturally occurring or are considered genetically modified.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): ASM members welcomed the provision allowing IBC-delegated member review for certain classes of experiments and urged NIH to retain this provision in the final policy. However, ASM members also expressed concerns that the removal of exemptions for low-risk work and biosafety level 1 (BSL-1) transgenic animals will increase the IBC's workload and reduce the amount of time that the IBC is able to spend reviewing higher-risk experiments. ASM members also raised that including experiments involving transient transfection of plasmid expression vectors in the scope of the policy could create increased workloads

for IBCs and investigators.
The draft policy requires that research involving novel or emerging biological agents (i.e agents that are not yet included in a Risk Group classification or the BMBL) must be reviewed and approved by both NIH and local IBCs. ASM members flagged that the requirement for NIH review could slow down research to understand emerging and novel pathogens and to develop medical countermeasures for these pathogens.

3. Continued utility of Risk Groups: Overall, ASM members appreciated that the scope of the draft policy is based on risk rather than a specific technology (i.e. research with recombinant or synthetic nucleic acid molecules). ASM members appreciated the inclusion of Risk Groups in the policy, affirming that Risk Groups are useful as a baseline for risk assessment and provide needed flexibility for institutions.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): ASM members raised that the requirement to post unredacted incident reports on a public-facing website, regardless of whether the incident merited reporting to NIH, could dissuade researchers from reporting near misses or other low-risk incidents to institutional officials and that this requirement could ultimately harm efforts to protect biosafety. The members' concern is that when researchers do not report low-risk incidents, this prevents IBCs and biosafety staff from proactively identifying areas where new or updated Standard Operating Procedures or improved training are needed. ASM members requested that NIH remove this requirement from the final policy and that NIH allow institutions to post redacted incident reports publicly.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The draft policy provides requirements and considerations for risk assessment for synthetic biological agents, and the references to synthetic biology in the policy are focused on infectious agents. ASM members noted that there are other uses for synthetic biology that do not involve infectious agents, such as the production of chemicals and peptides by bacteria and requested further clarification from NIH that the policy does not include these lower-risk activities.
The policy includes specific examples of experiments involving the influenza virus which must be conducted at a BSL-3. ASM members noted that influenza viruses do not represent the whole virology field, and NIH should consider other classes of viruses that may require use-case examples.

Uploaded File: ASM-NIH-Biosafety-Policy-Comments-2026.pdf

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Dr. Lyric Jorgenson
Director
NIH Office of Science Policy
9000 Rockville Pike
Bethesda, MD 20892

Re: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Dr. Jorgenson,
Thank you for the opportunity to respond to the Draft NIH Biosafety Policy Involving Biohazards. ASM is one of the oldest and largest life science societies with over 38,000 members in the U.S. and around the world, with many ASM members conducting research covered by NIH biosafety policies.

In response to NIH's call for feedback on the Biosafety Modernization Initiative, ASM convened a group of experts in biosafety and biosecurity who have decades of experience conducting research conducted by the policy, including research that may be considered high risk, and members with experience overseeing institutional biosafety programs and policies. This letter documents their feedback on the topics requested by NIH and additional areas for consideration.

General concerns
This policy is open to public comment at the same time as agencies are working to implement the US Government Policy for Stopping High Risk Life Sciences Research.[1] ASM members are concerned that requirements of the US Government Policy for Stopping High Risk Life Sciences Research will increase the workload of PIs, institutional biosafety staff and IBCs significantly. This feedback aligns with broader concerns regarding administrative burden. ASM members raised concerns that the draft NIH Biosafety Policy for Research Involving Biohazards will require increased administrative efforts to comply with the policy and requested that NIH ensure that the final NIH biosafety policy and the US Government Policy for Stopping High Risk Life Sciences

[1] United States Government Policy for Stopping High Risk Life Sciences Research. 2026. https://www.whitehouse.gov/wp-content/uploads/2026/07/USG-Policy-for-Stopping-High-Risk-Life-Sciences-Research_July-2026.pdf

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Research are aligned and do not add additional undue administrative burden for PIs and institutions. ASM acknowledges that NIH is currently soliciting feedback from the scientific community about reducing administrative burden associated with obtaining, maintaining and reporting on NIH extramural research funding, and encourages NIH to consider the impact of these proposed policies on administrative burden

In the September 2025 announcement for the Biosafety Modernization Initiative, NIH said that the initiative will provide an opportunity for institutional leadership to reassess whether their Institutional Biosafety Committees (IBCs) are receiving support and resources equal to other institutional committees, such as those that review human subjects research and the care and use of animals.[2] Institutional Animal Care and Use Committees and Institutional Review Boards often have more staff support and resources than IBCs at most institutions.[3] ASM requests that NIH work with institutions to ensure that IBCs have adequate resources to implement both the NIH biosafety policy and the US Government Policy for Stopping High Risk Research. ASM members also requested that NIH ensure that the requirements of both policies are complementary and do not create contradictory requirements.

Scope of Research Covered by the New Policy

While understanding that NIH has excluded plant pathogens from the proposed policy because of NIH's focus on human health, ASM members raised concerns that excluding plant pathogen research from NIH oversight could expose the nation's food supply to new risks. ASM requests that NIH work with USDA and other research agencies to ensure oversight over plant pathogen research is sufficient and ensure that the plant pathogen research oversight policies are complementary and not contradictory with oversight of other kinds of pathogen research.

Furthermore, ASM members requested clarification of several of the definitions in the proposed biosafety policy:

- The definition of "toxin" in the policy – "a protein or peptide produced by living organisms that causes harm in humans" -- is broad and could be interpreted to include allergens that humans experience in everyday life, like pollen.

[2] https://www.nih.gov/about-nih/nih-director/statements/nih-launches-initiative-modernize-strengthen-biosafety-oversight

[3] Johnson CM, Dobos KM. The Evolving Landscape of Institutional Biosafety Committees and Biosafety Programs: Results from a National Survey on Organizational Structure, Resources, and Practices. Appl Biosaf. 2019 Dec 1;24(4):213-219. doi: 10.1177/1535676019886175. Epub 2019 Dec 1. PMID: 36032060; PMCID: PMC9134475.

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- The policy covers "cells or organisms, other than plants, containing [infectious agents or prions]." However, all higher-level eukaryotic cells contain endogenous retroviruses. ASM members requested clarification that the policy covers cells that are infected whether lytically, latently or persistently.
- The definition of "wild type" and "novel agent or organism" could be subject to differing interpretations of what organisms, cell and viruses are naturally occurring or are considered genetically modified.[4]

Structure of Tiered Oversight

ASM members welcomed the provision allowing IBC-delegated member review for certain classes of experiments and urged NIH to retain this provision in the final policy. However, ASM members also expressed concerns that the removal of exemptions for low-risk work and biosafety level 1 (BSL-1) transgenic animals will increase the IBC's workload and reduce the amount of time that the IBC is able to spend reviewing higher-risk experiments. ASM members also raised that including experiments involving transient transfection of plasmid expression vectors in the scope of the policy could create increased workloads for IBCs and investigators. The draft policy requires that research involving novel or emerging biological agents (i.e agents that are not yet included in a Risk Group classification or the BMBL) must be reviewed and approved by both NIH and local IBCs. ASM members flagged that the requirement for NIH review could slow down research to understand emerging and novel pathogens and to develop medical countermeasures for these pathogens.

Continued utility of Risk Groups

Overall, ASM members appreciated that the scope of the draft policy is based on risk rather than a specific technology (i.e. research with recombinant or synthetic nucleic acid molecules). ASM members appreciated the inclusion of Risk Groups in the policy, affirming that Risk Groups are useful as a baseline for risk assessment and provide needed flexibility for institutions.

Effectiveness of compliance and enforcement mechanisms

ASM members raised that the requirement to post unredacted incident reports on a public-facing website, regardless of whether the incident merited reporting to NIH, could dissuade researchers from reporting near misses or other low-risk incidents to institutional officials and

[4] Askenasy I, Swain JEV, Ho PM, Nazeer RR, Welch A, Bényei ÉB, Mancini L, Nir S, Liao P, Welch M. 'Wild Type'. Microbiology (Reading). 2024 Aug;170(8):001495. doi: 10.1099/mic.0.001495. PMID: 39212644; PMCID: PMC11364142.

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that this requirement could ultimately harm efforts to protect biosafety. The members' concern is that when researchers do not report low-risk incidents, this prevents IBCs and biosafety staff from proactively identifying areas where new or updated Standard Operating Procedures or improved training are needed. ASM members requested that NIH remove this requirement from the final policy and that NIH allow institutions to post redacted incident reports publicly.

Feedback on implementation resources

The draft policy provides requirements and considerations for risk assessment for synthetic biological agents, and the references to synthetic biology in the policy are focused on infectious agents. ASM members noted that there are other uses for synthetic biology that do not involve infectious agents, such as the production of chemicals and peptides by bacteria and requested further clarification from NIH that the policy does not include these lower-risk activities.

The policy includes specific examples of experiments involving the influenza virus which must be conducted at a BSL-3. ASM members noted that influenza viruses do not represent the whole virology field, and NIH should consider other classes of viruses that may require use-case examples.

Conclusion

ASM appreciates the opportunity to provide feedback on the NIH Biosafety Policy for Research Involving Biohazards and appreciates NIH's efforts to broadly engage the scientific community in updating its biosafety policy. If you have any questions or would like to further discuss these comments, please contact Nicole Zimmerman, Senior Federal Affairs Officer, at nzimmerman@asmusa.org.

Thank you,



Amalia Corby
Director of Federal Affairs
ASM

467. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Government Agency

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious diseases

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Note - Unless otherwise indicated, for sections 1-6 the page numbers refer to the page numbers of the pdf generated when the draft policy is saved as a pdf.

a) “Well characterized cell lines” (Pg 10, Section IV-3) by themselves may not necessarily fall within any of the categories described under the scope of this policy - i.e. cell lines such as PC-12 (rat, ATCC), BHK-21 (hamster, ATCC) do not have agents that are known to cause disease in healthy humans. It may be appropriate to exempt work involving primary or immortalized non-recombinant cells lines that do not cause disease in healthy humans.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): a) Having a mechanism to exempt low-risk research may be appropriate (i.e. use of well-characterized cell lines, recombinant derivatives of low-risk pathogens that are not capable of replication or infection, research covered under III-F of the current NIH guidelines etc.). Having the PIs submit once to the IBC or its designated subcommittee for an official exempt determination may be sufficient for tracking, transparency, and accountability purposes. It may be appropriate to require a new submission if there is a change to the risk or containment requirements involved in the research. Periodic reviews post-approval maybe appropriate, but some low-risk research may not need the same level of oversight as higher risk research.

b) Since the Federal Select Agent Program (FSAP) already oversees the use of biological select agents and toxins (Pg 12, https://www.selectagents.gov/) having the IBC oversee them as well may be a duplication of review efforts and perhaps inappropriate as described below.

b.i) Under the FSAP, the CDC and USDA already review research involving non recombinant biological select agents and toxins. This review requires specialized expertise and follows stringent reporting mandates. Wouldn’t it be appropriate to defer to the FSAP review for select agent research rather than mandate that the IBC provide a duplicate review? This would be similar to deferring to FDA for some

research.

b.ii) What action should the investigator take if the recommended actions provided under the FSAP and IBC are not in agreement? Does the recommendations of one authority take precedence over the other? If so, isn't it appropriate to defer to the superseding authority in the first place?

b.iii) It may be appropriate to have the IBC oversee some work involving recombinant biological select agents and toxins as that is currently already being done. However, a duplication of review efforts can be prevented and clarity of guidance for PI can be maintained if the same type of research is not reviewed by both the IBC and under the FSAP.

c) Under incident reporting (Pg 7) states "Any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approval" requires immediate notification to NIH within 24 hours and a full incident report within 30 days.

c.i) If "failure to maintain approval" refers to failure to comply with the safety regulations outlined in the IBC approval for research involving an infectious agent especially an agent considered to be RG 3 or 4 it may be appropriate to notify the NIH immediately and provide a full incident report.

c.ii) The verbiage "failure to maintain approval" if applicable to annual reviews it would imply that even a delay of two days for approving an annual review for low-risk research (i.e. work involving non-infectious, non-viable agents) would trigger an incident that requires immediate notification to NIH. Considering the low risk of the research, isn't it more appropriate to record such an incident as a relatively less urgent issue? If this was not the intent of this statement then it would be helpful if the language was clearer.

3. Continued utility of Risk Groups: None.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): None.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: a) Per the draft NIH policy all incident reports should be published on a public facing website. There is no dispute that all incidents should be recorded and maintained as a part of the institutional record and perhaps periodically submitted to NIH as individual or aggregate records. However, it would seem that publishing all minor events on the public facing website retracts from any benefit that public records would serve as explained below.

a.i) Publishing a breach of containment of an infectious agent or an incident where an infected person required medical care in a hospital may be beneficial for the public. Conversely, knowing how many needlesticks from a saline syringe occurred in a lab does not create a safety concern for the public. However, when both of these incidents are lumped together, then the important incidents get buried under too much data. I understand they will be recorded as separate incidents. But every additional record only adds to the volume of information requiring the public to sift through lots of data to find anything meaningful to them. In my opinion, if publication is necessary, it would be beneficial to publish only incidents that may potentially compromise the safety of the community. All other incident reports

should be maintained as a part of the institutional and/or NIH record and can be available upon request in compliance with Freedom of Information Act (FOIA). Publishing aggregate incidents for minor incidents may be a more meaningful alternative to publishing individual minor incidents.

a.ii) Indiscriminately publishing all incidents online creates a huge administrative burden with little benefit to the public.

a.iii) The general public may not always be able to interpret the significance of a lab incident in terms of its harm to the surrounding community and environment. Even minor incidents may be perceived as disproportionally harmful and may contribute to public unrest and fear. I.e. some select agent work can be safely conducted at BSL 2 with the necessary safety precautions in place. However, while an individual with expertise may be able to distinguish the difference between low-risk work and high-risk work, an individual without the necessary expertise may perceive the risk posed by a non-infectious, non-viable select agent derivative the same risk as its infectious counterpart. Thus, leading to unnecessary public fear. This may be an unintended consequence of publishing incident reports in a public facing website. It may be advisable to have a qualified individual/s review incident reports rather than open every minor infraction up for public comment.

a.iv) It would be helpful to understand the benefit of publishing all meeting minutes and incident reports on a public facing website. The IACUC and IRB do not publish any of those documents in a public website by default although they too are subject to FOIA.

6. Other feedback relevant to this resource: a. In Section III (pg. 5) policy states “Assurances are approved by NIH for a period of up to four years.”. Verbiage should be clarified as to whether Assurances are approved for 4 years or if NIH may choose to approve it for fewer years under certain circumstances.

b. Under IBC functions (pg. 6) the policy state that “No member of the IBC may be involved in the review or approval of a project in which they are or expect to be engaged, or in which they have a direct financial or any other conflict of interest, except to provide information requested by the IBC to facilitate their review. Such members can be counted for purposes of establishing a voting quorum for the meeting even if they recuse themselves from the final determination related to the project.”. The verbiage is unclear. How can recusing members be meaningfully counted for a “voting quorum” if they don’t contribute to the vote?

c. Under Section IV-1 and IV-2, “Categories of Oversight for Research Based on Risk” (pg. 9-11) the same criteria are repeated in multiple categories. Therefore, the criteria applicable to each section should be clarified. See (i) and (ii) below,

c.i) Section IV-1: “Initial requests for NIH to lower containment for research involving wild type or genetically modified RG3 or RG4 biological agents (e.g., experiments with attenuated or replication-defective constructs).” AND
c.ii) Section IV-2: “Research involving RG3 or RG4 wild-type biological agents.”

d) Section IV-2 (pg. 10) states that “Research with primary cells that may be contaminated by adventitious agents.”. If a researcher, not associated with an FDA approved study, wanted to use

specimens such as blood or sputum from human participants that are, for example, vaccinated with a live-attenuated virus (i.e. MMR, FluMist), do they need IBC oversight?

Uploaded File: Draft-NIH-Biosafety-Policy-2026_Individual-Comments.pdf

Description: Attached is the word document with the same comments as above.

Comments on Draft NIH Biosafety Policy for Research Involving Biohazards (Aug 2026)

Unless otherwise indicated, for sections 1-6 the page numbers refer to the page numbers of the pdf generated when the draft policy is saved as a pdf.

1. **Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed.**

    a. "Well characterized cell lines" (Pg 10, Section IV-3) by themselves may not necessarily fall within any of the categories described under the scope of this policy - i.e. cell lines such as PC-12 (rat, ATCC), BHK-21 (hamster, ATCC) do not have agents that are known to cause disease in healthy humans. It may be appropriate to exempt work involving primary or immortalized non-recombinant cells lines that do not cause disease in healthy humans.

2. **Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local).**

    a. Having a mechanism to exempt low-risk research may be appropriate (i.e. use of well-characterized cell lines, recombinant derivatives of low-risk pathogens that are not capable of replication or infection, research covered under III-F of the current NIH guidelines etc.). Having the PIs submit once to the IBC or its designated subcommittee for an official exempt determination may be sufficient for tracking, transparency, and accountability purposes. It may be appropriate to require a new submission if there is a change to the risk or containment requirements involved in the research. Periodic reviews post-approval maybe appropriate, but some low-risk research may not need the same level of oversight as higher risk research.

    b. Since the Federal Select Agent Program (FSAP) already oversees the use of biological select agents and toxins (Pg 12, https://www.selectagents.gov/) having the IBC oversee them as well may be a duplication of review efforts and perhaps inappropriate as described below.

        i. Under the FSAP, the CDC and USDA already review research involving non-recombinant biological select agents and toxins. This review requires specialized expertise and follows stringent reporting mandates. Wouldn't it be appropriate to defer to the FSAP review for select agent research rather than mandate that the IBC provide a duplicate review? This would be similar to deferring to FDA for some research.

        ii. What action should the investigator take if the recommended actions provided under the FSAP and IBC are not in agreement? Does the recommendations of one authority take precedence over the other? If so, isn't it appropriate to defer to the superseding authority in the first place?

        iii. It may be appropriate to have the IBC oversee some work involving recombinant biological select agents and toxins as that is currently already being done. However, a duplication of review efforts can be prevented and clarity of guidance for PI can

be maintained if the same type of research is not reviewed by both the IBC and under the FSAP.

c. Under incident reporting (Pg 7) states "Any compliance violations at any BSL/ABSL, such as failure to obtain or maintain IBC approval" requires immediate notification to NIH within 24 hours and a full incident report within 30 days.

   i. If "failure to maintain approval" refers to failure to comply with the safety regulations outlined in the IBC approval for research involving an infectious agent especially an agent considered to be RG 3 or 4 it may be appropriate to notify the NIH immediately and provide a full incident report.

   ii. The verbiage "failure to maintain approval" if applicable to annual reviews it would imply that even a delay of two days for approving an annual review for low-risk research (i.e. work involving non-infectious, non-viable agents) would trigger an incident that requires immediate notification to NIH. Considering the low risk of the research, isn't it more appropriate to record such an incident as a relatively less urgent issue? If this was not the intent of this statement then it would be helpful if the language was clearer.

3. Continued utility of Risk Groups (RGs) as a baseline for risk assessment, particularly when agents are being genetically modified, versus use of Biosafety Levels (BSL) outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).

None.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions)

None.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates

a. Per the draft NIH policy all incident reports should be published on a public facing website. There is no dispute that all incidents should be recorded and maintained as a part of the institutional record and perhaps periodically submitted to NIH as individual or aggregate records. However, it would seem that publishing all minor events on the public facing website retracts from any benefit that public records would serve as explained below.

   i. Publishing a breach of containment of an infectious agent or an incident where an infected person required medical care in a hospital may be beneficial for the public. Conversely, knowing how many needlesticks from a saline syringe occurred in a lab does not create a safety concern for the public. However, when both of these incidents are lumped together, then the important incidents get buried under too much data. I understand they will be recorded as separate incidents. But every additional record only adds to the volume of information requiring the public to sift through lots of data to find anything meaningful to them. In my opinion, if

publication is necessary, it would be beneficial to publish only incidents that may potentially compromise the safety of the community. All other incident reports should be maintained as a part of the institutional and/or NIH record and can be available upon request in compliance with Freedom of Information Act (FOIA). Publishing aggregate incidents for minor incidents may be a more meaningful alternative to publishing individual minor incidents.

ii. Indiscriminately publishing all incidents online creates a huge administrative burden with little benefit to the public.

iii. The general public may not always be able to interpret the significance of a lab incident in terms of its harm to the surrounding community and environment. Even minor incidents may be perceived as disproportionally harmful and may contribute to public unrest and fear. I.e. some select agent work can be safely conducted at BSL 2 with the necessary safety precautions in place. However, while an individual with expertise may be able to distinguish the difference between low-risk work and high-risk work, an individual without the necessary expertise may perceive the risk posed by a non-infectious, non-viable select agent derivative the same risk as its infectious counterpart. Thus, leading to unnecessary public fear. This may be an unintended consequence of publishing incident reports in a public facing website. It may be advisable to have a qualified individual/s review incident reports rather than open every minor infraction up for public comment.

iv. It would be helpful to understand the benefit of publishing all meeting minutes and incident reports on a public facing website. The IACUC and IRB do not publish any of those documents in a public website by default although they too are subject to FOIA.

6. Feedback on the implementation resources and areas in which additional guidance would be beneficial.

a. In Section III (pg. 5) policy states "Assurances are approved by NIH for a period of up to four years.". Verbiage should be clarified as to whether Assurances are approved for 4 years or if NIH may choose to approve it for fewer years under certain circumstances.

b. Under IBC functions (pg. 6) the policy state that "*No member of the IBC may be involved in the review or approval of a project in which they are or expect to be engaged, or in which they have a direct financial or any other conflict of interest, except to provide information requested by the IBC to facilitate their review. Such members can be counted for purposes of establishing a voting quorum for the meeting even if they recuse themselves from the final determination related to the project.*". The verbiage is unclear. How can recusing members be meaningfully counted for a "voting quorum" if they don't contribute to the vote?

c. Under Section IV-1 and IV-2, "Categories of Oversight for Research Based on Risk" (pg. 9-11) the same criteria are repeated in multiple categories. Therefore, the criteria applicable to each section should be clarified. See (i) and (ii) below,

i. Section IV-1: “Initial requests for NIH to lower containment for research involving **wild type** or genetically modified **RG3 or RG4 biological agents** (e.g., experiments with attenuated or replication-defective constructs).” AND

ii. Section IV-2: “Research involving **RG3 or RG4 wild-type biological agents.**”

d. Section IV-2 (pg. 10) states that “*Research with primary cells that may be contaminated by adventitious agents.*”. If a researcher, not associated with an FDA approved study, wanted to use specimens such as blood or sputum from human participants that are, for example, vaccinated with a live-attenuated virus (i.e. MMR, FluMist), do they need IBC oversight?

468. Public Responsibility in Medicine and Research (PRIM&R)

I am responding: On behalf of an organization

Name: Daniel McLean

Name of Organization: Public Responsibility in Medicine and Research (PRIM&R)

Type of Organization: Non-Profit Research Organization

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attached.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see attached.

3. Continued utility of Risk Groups: Please see attached.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see attached.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attached.

6. Other feedback relevant to this resource: Please see attached.

Description: PRIMR comment

469. Kelly Kim

I am responding: On behalf of myself

Name: Kelly Kim

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Professional

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of this policy is inconsistent and poorly defined.
Definitions need to be expanded and cover key terms like biohazard and laboratory research to ensure that the implementation of the policy can be executed, consistent, and enforceable. In addition to creating clarity expanding the definitions will create stronger internal consistency for the policy as a whole.
As it stands, this policy is solely focused on human health while the policy it supersedes covered activities conducted in animal facilities, greenhouses, agricultural settings, field studies, and other nonlaboratory environments where biological hazards are present. This creates a gap in scope that the policy should address whether by extending the scope or coordinating with other policies/ institutions.
The scope of biohazard is poorly defined and should be extended to cover more than just human pathogenicity.
The scope of laboratory needs to be better defined. As it stands it is unclear whether clinical sites and GMP facilities will be under this policy.
The exclusion of plants may create oversight gaps. Clarification is needed regarding how genetically modified plants, plant pathogens, plant-associated toxins, agricultural pests, and related organisms will be addressed. A comprehensive biosafety framework should reflect a One Health approach that considers human, animal, plant, and environmental health impacts.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A true risk based tiered oversight would allow for institutions to handle low risk activities and reserving federal reporting and review requirements for activities presenting the greatest potential risk, thus not overwhelming the system and creating flexibility in often complex situations.
The policy should delineate the process for a protocol renewal and that of a new protocol, accounting for risk and program changes.
Th policy should clarify what is reportable and what could be handled by the institution. A tiered approach to incident reporting would help focus federal oversight on significant events while reducing

administrative burden associated with minor incidents that do not involve exposure, environmental release, or significant risk.
The data shared in these reports should be deidentified and shared in a database or annual report so institutions can understand how they stack up nationally. This information can be used to generate research and better safety precautions, and for buy in at an institutional level to garner better risk protection overall.

3. Continued utility of Risk Groups: Risk groups are a good starting point, but do not adequately capture all risks associated with genetically modified organisms, novel constructs, etc. The final policy should preserve experiment-specific and site-specific risk assessments.
Additional guidance is needed regarding how institutions should determine risk groups under the proposed framework, particularly because the draft does not appear to identify whether information currently provided in Appendix B of the NIH Guidelines will still apply. BMBL does not include risk groups, and in some cases provides a BSL range. Clear guidance regarding the relationship between Risk Groups, project-specific risk assessment, and Biosafety Levels would improve consistency across institutions and in implementation of the policy.
Rigid attachment to universal minimum BSL-2 for GDMOs does not map well to arthropod, aquatic, greenhouse, ecological, or other specialized containment systems. Allowing institutional risk assessments to stand in for a strict adherence to mapped levels will create better safety and research overall.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The policy's expanded public posting requirements risk exposing proprietary research details, personal information, security-sensitive information, and context that may be misinterpreted. It is also likely to discourage prompt reporting of minor events and near misses, an important aspect of a strong safety culture. Some research areas are prone to security concerns for researchers involved, were identification, even generally, could put their personal safety at risk. NIH should require standardized public summaries that are de-identified and focused on oversight outcomes, corrective actions, and lessons learned, while detailed records remain available to NIH for oversight and through existing lawful disclosure processes.
A timeline for redaction and data retention should be outlined in the policy.
The policy should emphasize education and technical tools and model practices as voluntary feels like a misnomer in this case. Additionally, NIH should provide practical tools, templates, decision trees, training resources, and examples that can be implemented regardless of funding source to increase adoption.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The policy would benefit from clearer definitions, timelines, and specific reporting thresholds. Additional guidance is needed regarding whether incidents such as spills contained within primary containment, minor events without exposure or release, or needlesticks involving sterile needles require reporting at each BSL.
The new meeting minutes require significant administrative time investment, which is duplicative.
As previously mentioned, public posting of incident reports, especially as currently poorly defined, will discourage reporting and undermine hard won safety culture. Significant consideration should be given to de-identification standards, redaction requirements, aggregation of minor events, and protections for security-sensitive information.
This data should be aggregated in a searchable database to benefit safety nationwide, but only if it can be done so without violating researchers' work and right to privacy.

6. Other feedback relevant to this resource: This policy will require a great deal of work for institutions to implement. It requires revision of policies, new training, and a great deal more. Thus, phased implementation and implementation resources are required to minimize disruption of current research and ensure policy compliance.
The policy should allow for flexibility as scientific enterprises are rarely one-size fits all.
A glossary is needed with definitions that are clear through the whole policy.

470. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of research "conducted at or sponsored by the institution" needs precise definition. It is critical to clarify how this applies to non-NIH-funded research, affiliates, leased space, off-site collaborations, teaching, downstream clinical sites, and products originally developed with NIH funding.

The proposed six-month implementation timeline is insufficient and unrealistic for institutions to adequately comply, modify electronic systems, or revise local procedures. I recommend extending this to a minimum of 12 to 24 months and utilizing a phased, risk-based transition with established milestones that begin only after final guidance and required templates are made available.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Exempt activities must be clearly specified, or a framework for institutional discretion must be outlined. I request explicit identification of activities requiring no submission, documentation only, or prior approval, including the treatment of formerly exempt activities like the breeding of certain transgenic rodents or routine well-characterized cell lines. An exempt category section for lower-risk agents should be created to prevent unnecessary mandatory delegated IBC approval for minimal-risk activities.

3. Continued utility of Risk Groups: Risk Group (RG) describes agent characteristics and hazards, whereas Biosafety Level (BSL) describes containment conditions; these terms should not be treated as interchangeable. RGs should serve as a starting point for risk assessment, but they should not independently dictate review levels that conflict with a site-specific and experiment-specific risk assessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The current incident reporting requirements raise significant security and privacy concerns. Public posting of identified incident reports could expose proprietary research, personal medical information, and security-sensitive details, potentially discouraging a culture of prompt, voluntary near-miss reporting. I recommend

standardizing de-identified public summaries with clear redaction rules. Furthermore, the policy must clarify whether any event occurring in a BSL-3 or BSL-4 facility is reportable, regardless of whether it actually involves a biohazard or a credible biological exposure (e.g., minor spills or backup containment failures).

6. Other feedback relevant to this resource: To ensure national consistency and alleviate administrative burden, NIH should provide final, standardized templates for the Biosafety Assurance, risk assessments, meeting minutes, and incident reporting before the policy takes effect. We strongly recommend piloting these templates with diverse institutions and clearly distinguishing between required, conditional, and optional fields.

Institutions require clear decision trees or tables to determine the type of review (e.g., full committee, delegated, administrative, or NIH review) and to navigate incident reporting requirements. These tools should resolve overlapping categories, establish clear precedence rules between review pathways, and provide worked examples to guide institutional determinations.

The policy must align the expanded responsibilities of the BSO with explicit authority, independence, and institutional support. Minimum qualifications, institutional access, reporting relationships, and the authority to require corrective measures, escalate unresolved risks, and stop unsafe work must be clearly defined.

Clear expectations regarding occupational health are needed. The policy should include explicit triggers, assigned authorities, and distinct boundaries explaining how the Principal Investigator's (PI) responsibility for safe research interfaces with the institution's overall responsibility for developing, communicating, and providing occupational health services.

I request explicit rules mapping retention requirements to specific record types (e.g., protocols, risk assessments, delegated reviews, assurances, and meeting minutes). The policy should outline the triggering event, retention period, public availability period, and it should clarify requirements for non-NIH-funded work or records spanning multiple awards.

471. Richard Baumann

I am responding: On behalf of myself

Name: Richard Baumann

Name of Organization: NIH Bethesda Campus

Type of Organization: Government Agency

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: We have prepared and submitted collated comments from our division as a whole, so those should be weighted significantly when reviewed. There are two points I wanted to personally comment on individually with the experience of being the Biosafety Officer at the NIH/Bethesda area for the last twenty years. Point (1) I applaud the OSP for encompassing the registrations of all potential pathogens in the new policy for Research Involving Biohazards- the NIH/Bethesda has been doing this since inception for over 50 years. In my experience registering investigators working with 'common' biological materials over the last two decades (human cells, cell lines, toxin, bacteria and viruses with work procedures approved at BSL-2)- I can share that for the vast majority of cases (over 90%), research activities with the material may not change for many years, and new procedures are not introduced that might change risk. With todays electronic registration systems, the registrations are a living document with annual reviews performed every year- keeping the registration up to date as opposed to a "snapshot in time". Admin changes (to personnel and laboratory) are made in real time, and any substantive changes that may introduce new risk can be submitted as a formal amendment and weighed by the IBC. Mandating a 3yr expiration period for all registrations simply because a date has passed is forcing regulatory constraints without safety benefit. The suggested time frame should be doubled to 6 years at least- to be less exhausting, or institutions should be able to decide their approach based on their systems, practices, research profile, and resources available to address realistic risks. Perhaps identifying a tiered approach for this deadline may be beneficial, with certain research activities of lower risk having longer permissible deadlines than other higher risk activities, or potentially risk introducing activities: such as when performing recombinant work in RG-3 and RG-4 organisms- where complete ('de novo') re-review of such research activities may be beneficial.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Regarding the tiered oversight approach as described in Section IV of the proposed policy, I am in favor with the OSP identifying lower risk activities that may be delegated to individuals or Subgroups of the IBC members. But in general there is new mandated oversight now described for the IBC to review all work with genetically modified organisms, and particularly also to have to review research with transgenic organisms that can be conducted safely at BSL-1/ABSL-1 that is newly required. This had previously been

removed successfully from the NIH Guidelines because it was determined (by OSP) that such oversight came with no safety benefit for the researchers. Research with established TG rodents and other species is quite commonplace and can be performed safely under established CORE and animal facility SOPs. Going back to this old requirement will be constraining not only to researchers but the entire review process. No estimation has been made to the additional resources it will take to comply with these requirements. It is apparent that regulatory efforts should be concentrated to where oversight will be most beneficial, and these new requirements as reintroduced in this proposed policy is in stark contrast to the stated goal of the policy "to expand the scope of the NIH Guidelines to all biohazards, while removing red tape for low-risk research". Once TG animals have been registered and found to be safe to work with, a requirement to register their use in subsequent experiments is red-tape and unnecessary "paperwork" from safety- which is a perception we work very hard to overcome- we do this by addressing realistic risks and making meaningful assessments to benefit research activities. Identifying oversight concerns in this regard would be most beneficial to understand why it would be newly required in the policy.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

472. PRIM&R

I am responding: On behalf of an organization

Name: Daniel McLean

Name of Organization: PRIM&R

Type of Organization: Non-Profit Research Organization

Role: Bioethicist

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached. Prior submission did not appear to include attachment, so I have attempt to send again.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

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Description: PRIMR

PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

October 19, 2026

Office of Science Policy
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Submitted electronically

Re: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards; release date, August 19, 2026 (NOT-OD-26-112)

To the NIH Office of Science Policy:

Public Responsibility in Medicine and Research (PRIM&R), which has more than 3,200 active members throughout the research enterprise, appreciates the opportunity to respond to the NIH on this matter. PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science. Our perspective is informed by the experiences of professionals responsible for implementing federal research regulations across academic, healthcare, government, and independent research institutions.

NIH states that it is seeking public input on its "Draft NIH Biosafety Policy for Research Involving Biohazards, which, when finalized, will supersede the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules."[1]

According to the draft policy, "As the world's largest public funder of biomedical research, NIH is committed to ensuring that gold-standard science is conducted under gold-standard biosafety conditions. The purpose of the NIH Biosafety Policy for Research Involving Biohazards (the Policy) is to achieve this goal by setting forth requirements for federal and local institutional oversight of biomedical research involving biohazards, and to help ensure the safe, responsible, and secure conduct of such research."[2]

The draft NIH Biosafety Policy describes Institutional Biosafety Committee (IBC) review of certain clinical research, including challenge studies with RG2 or higher wild-type agents. NIH states that it aims to reinforce consistency with IRBs, but the draft does not describe how IBC and IRB review should be coordinated. PRIM&R requests guidance on review sequencing, information sharing between committees, and whether and how biosafety information should be addressed in the informed consent document.

[1] "Request for Information"; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
[2] "Background"; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

Further, the draft NIH Biosafety Policy requires IBC review and approval for research with primary cells that may be contaminated by "adventitious agents." It is unclear, however, whether NIH intends this category to include research with human tissue and specimens, which may also be subject to IRB review. We request NIH clarify the intended scope.

With respect to incident reporting, PRIM&R notes that certain incidents in clinical research may be reportable both under human subjects regulations and under the draft policy's requirement to notify NIH within 24 hours of incidents that pose a significant risk to human health. These obligations involve different committees, different timelines, and potentially different federal agencies. The draft policy does not appear to address how they should be coordinated. PRIM&R requests guidance on harmonizing these reporting processes.

Lastly, the draft NIH Biosafety Policy states, "any research subject to this Policy that is also under the regulation or purview of another federal agency may proceed under the oversight of the other federal agency once approvals or other applicable clearances have been obtained."[3] The draft also states that "clinical research cannot be initiated until IBC, and all other applicable institutional and regulatory authorization(s) and approvals have been obtained." [4] The draft policy does not explain, however, how these provisions apply to FDA-regulated trials, including whether IBC review is still required. PRIM&R requests that NIH clarify these requirements, as IRBs and institutions will need this information to fulfill their oversight responsibilities and avoid potential duplicative or conflicting review requirements.

As biosafety oversight continues to evolve, particularly in light of ongoing discussions around dual-use research of concern and the expanding scope of federally funded biomedical research, PRIM&R looks forward to serving as a resource and thought partner to NIH and other federal agencies on these issues.

Thank you for your consideration of these comments.

Sincerely,



Ivy R. Tillman, EdD, CIP
Executive Director
Public Responsibility in Medicine and Research (PRIM&R)

[3] Section II, "Scope"; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html
[4] Section IV-2, "Research That Requires IBC Review and Approval Before Initiation"; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

473. The University of Texas System

I am responding: On behalf of an organization

Name: Cody Willming

Name of Organization: The University of Texas System

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): The University of Texas System

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: UTS_NIH-Biosafety-Comments-Submitted-10.19.2026.pdf

The University of Texas System

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October 19, 2026

Cari Young, Sc.M., Director
Biosafety, Biosecurity, and Emerging Biotechnology Policy Division
Office of Science Policy
National Institutes of Health
Bethesda, Maryland 20892

Submitted electronically via osp.od.nih.gov
RE: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Director Young:

The University of Texas System ("UT System") submits the following comments in response to NIH Notice NOT-OD-26-112 requesting public input on the Draft NIH Biosafety Policy for Research Involving Biohazards. UT System comprises 13 institutions conducting research across a broad spectrum of disciplines. UT institutions collectively conduct more than $1 billion worth of NIH-funded research annually and have extensive experience securely managing biohazardous material at multiple safety levels.

UT System and its institutions are strongly committed to the highest standards of biosafety and biosecurity. We support NIH's goal of modernizing the biosafety oversight framework to reflect the evolving nature of biomedical research. We echo comments offered by the Association of American Medical Colleges (AAMC) and offer the following feedback to strengthen the clarity, consistency, and administrability of the proposed policy, around six key areas:

1. Scope and Definition of Biohazards (Section II)

The definition of "biohazard" requires clarification to ensure consistent application across the research enterprise. Specifically, UT System recommends that NIH:

- Clarify whether the scope includes bloodborne pathogens (BBPs), environmental samples, animal-only pathogens, and agents with uncertain pathogenicity, as these categories appear implicitly referenced in other sections but are not addressed by the stated definition.
- Resolve inconsistencies in the policy's "known or potential risk to human health" threshold with sections that reference zoonotic agents, GDMOs presenting environmental/ecological risks, and animal-related procedures, to clarify which activities require IBC oversight.
- Address the policy's broad application to all research at an NIH-funded institution—not just NIH-funded projects—and the significant compliance implications this creates for research funded by other sponsors.
- Provide a distinct definition and review pathway for research conducted in clinical settings, which do not conform to BSL containment levels but are otherwise included in the policy's scope.

2. Tiered Oversight and IBC Review (Sections IV-1 through IV-3)

UT System supports the tiered oversight framework and its risk-calibrated approach. To improve administrability, we request NIH address the following:

- Establish a clear mechanism and timeline for NIH review of emerging, novel, and zoonotic agents lacking an established Risk Group (RG) classification or containment level in the BMBL. Without defined timeframes, institutions and investigators cannot plan for the additional administrative burden.
- Clarify whether NIH-published determinations on higher-risk agents would eliminate the need for individual protocol submissions, or whether separate submissions would remain required.
- Define whether inactive toxin derivatives, isolated subunits, and nucleic acids encoding toxins are classified as "toxins," "genetic modifications," or both, and specify the review tier applicable to each.
- Allow institutions flexibility in defining the scope of "minor amendments" eligible for delegated review and to specify whether non-voting IBC members may conduct delegated reviews.

3. Risk Group Classifications

UT System agrees that Risk Group classifications remain an essential foundation for biosafety risk assessments and support their continued use. We encourage NIH to:

- Establish and maintain a dynamic, publicly accessible RG classification database that is updated in a timely manner as NIH completes reviews of novel and emerging agents.
- Provide expanded implementation guidance with concrete risk assessment examples and risk mitigation outlines to ensure consistent application across institutions.

4. IBC Meeting Minutes and Documentation (Section V)

The proposed documentation and public transparency requirements present significant practical concerns as currently written. We respectfully request NIH incorporate the following clarifications to avoid confusion and prevent the unintentional disclosure of information protected under state and federal law:

- Expertise Documentation: Requiring IBC minutes to document individual members' expertise is duplicative where an institution maintains a publicly available IBC roster. NIH should allow the roster to satisfy this requirement.
- Project Descriptions: NIH should clarify the expected level of project detail in publicly available IBC minutes while ensuring that proprietary, commercially sensitive, or pre-publication research information is appropriately protected.
- Privacy and PII: Publicly available minutes must not contain personally identifiable information. NIH should establish clear standards for what must be reported vs. what may be redacted.
- Required vs. Recommended: The draft should distinguish between requirements and recommendations when referencing items "to the maximum extent possible," as this ambiguity creates compliance uncertainty.

THE UNIVERSITY OF TEXAS AT ARLINGTON · THE UNIVERSITY OF TEXAS AT AUSTIN · THE UNIVERSITY OF TEXAS AT DALLAS
THE UNIVERSITY OF TEXAS AT EL PASO · THE UNIVERSITY OF TEXAS PERMIAN BASIN · THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY
THE UNIVERSITY OF TEXAS SAN ANTONIO · STEPHEN F. AUSTIN STATE UNIVERSITY · THE UNIVERSITY OF TEXAS AT TYLER
THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER · THE UNIVERSITY OF TEXAS MEDICAL BRANCH AT GALVESTON
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON · THE UNIVERSITY OF TEXAS MD ANDERSON CANCER CENTER

5. Incident Reporting

UT System supports robust incident reporting to advance biosafety learning system-wide, and recommends the following modifications:

- Confidential, Not Public Posting: Incidents should be reported to the National Biosafety Data and Safety Analysis Center rather than posted on a public-facing institutional website. Mandatory public posting may deter reporting of near-misses and increase HIPAA and privacy liability.
- Scope of Reportable Incidents: The definition of reportable incidents should focus on biosafety-relevant events (biohazard exposure, release or potential release, equipment failures resulting in exposure, and significant near-misses). Routine occupational safety incidents unrelated to biohazards should be excluded.
- Confidential vs. Public Information: The policy should specify which information is provided to NIH confidentially vs. which information is intended for public disclosure. Institutions should retain authority to redact identifying information from any public-facing summary.

6. Administrative Burden and Renewal Cycle

The proposed three-year renewal cycle would substantially increase administrative burden on investigators and IBCs. Institutions currently operating under a five-year cycle could experience a near-doubling of renewal workload, straining biosafety program staffing and resources. UT System recommends:

- Adopting a risk-based or tiered renewal schedule that permits longer renewal intervals for lower-risk research with demonstrated compliance histories, while reserving more frequent review for higher-risk protocols.
- Clarifying the requirement to "periodically review" approved research beyond the formal renewal cycle, including specifying the frequency, scope, and triggers that would require notification to the IBC.

UT System thanks NIH for the opportunity to provide input and commends the agency's commitment to strengthening biosafety oversight. We appreciate NIH's consideration of these comments and are eager to work collaboratively with NIH to develop a final policy that is rigorous, clear, and administrable for the research institutions that must implement it.

Sincerely,

[redacted]

Archie L. Holmes Jr., Ph.D.
Executive Vice Chancellor for Academic Affairs
The University of Texas System

[redacted]

Brian Dean, M.B.A., M.P.H.
Executive Vice Chancellor for Health Affairs
The University of Texas System

CC: John M. Zerwas, M.D., Chancellor
CC: Julia Rathgeber, J.D., Deputy Chancellor and Senior Policy Advisor
CC: Melissa Villarreal García, J.D., Deputy Vice Chancellor and Chief of Staff

474. Virginia Commonwealth University

I am responding: On behalf of an organization

Name: James Spencer

Name of Organization: Virginia Commonwealth University

Type of Organization: Academic Institution

Role: Other

Role - Other: Associate Director, Environmental Health & Safety/IBC Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

475. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The draft policy states that IBC approval may not exceed three years, after which the investigator must submit a de novo registration for review. Mandatory de novo review every three years would substantially increase workload for investigators, BSOs, IBC staff, committee members, and institutional officials. Conversely, a five-year cycle aligns more closely with the evolution of many funded research programs. A risk-based de novo renewal is recommended, and NIH should permit IBC approvals for up to five years, with temporary extensions allowed while institutional review is in progress. Additionally, existing expiration dates should be grandfathered in rather than requiring early renewal to conform to the new policy.

Revise the scope and definition of “biological agent” to refer to wild-type biological agents “associated with disease in healthy adult humans,” and state expressly in the scope section that research involving wild-type RG1 biological agents is not subject to the policy.

The policy does not preserve the exemptions developed under Section III-F and Appendix C of the current NIH Guidelines. The current exemptions incorporates decades of experience and risk based determinations of research activities that do not present a significant risk to human health or the environment. Without an explicit exclusions section, routine activities involving well-characterized host-vector systems, established cell lines, transgenic rodents, and other commonly used research systems could require IBC approval even though the same activities are currently exempt from the NIH Guidelines, which would greatly increase the burden on PIs, BSOs, and IBC members. NIH should include an “Exclusions” section in the policy which retains the exemptions in the current NIH Guidelines. NIH should also consider extending the exclusions to established low-risk model organisms and laboratory strains, including Caenorhabditis elegans, Drosophila melanogaster, and Escherichia coli B21. Additionally, NIH should establish a formal, transparent mechanism for adding, modifying, or withdrawing exclusions based on accumulated experience, scientific evidence, and technological development.

The draft defines a toxin as a protein or peptide produced by a living organism that causes harm in

humans. Plant-derived toxins should be excluded for consistency, since plants are excluded from the genetic-modification components of the policy's scope. Additionally, NIH should retain the established threshold of a human LD50 of less than 100 nanograms per kilogram body weight to identify exceptionally potent toxins and genes encoding exceptionally potent toxins that warrant heightened federal oversight. Toxins above that threshold should be excluded from the policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Risk groups are poorly suited to laboratory use because they describe risk to healthy adults in the community and reflect community exposure rather than laboratory conditions. Risk group assignments have been removed from the NIH Guidelines and are not comprehensively provided in the BMBL. If risk groups will be retained, NIH should provide a definitive source or clear criteria for assigning risk groups. Without standardized risk group classifications, institutions may reach different conclusions for the same agent, reducing consistency across the research community.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reports contain concentrated information about a specific event and the people, laboratory, and research activities involved. Public posting may discourage reporting of minor incidents or suspected exposures, especially for smaller laboratories where the combination of PIs name, biological agent, and personnel position may allow identification of the affected individual. Public posting should be limited to a summary of incidents that are reportable to NIH. Do not require the public summary to identify the Principal Investigator, department, medical response, or other details that could permit identification.

The policy includes a requirement to report delegated approvals "in full" in IBC meeting minutes, however it is unclear what is meant by "reported in full." NIH should clarify what information must be included for a delegated approval to be "reported in full." Institutional registration number, general research category, type of submission or amendment, broad biological materials, containment level, approval date, and material conditions should be sufficient to meet this requirement. Additionally, purely administrative amendments to add personnel or change room location that do not affect the biosafety risk assessment should be excluded from reporting in public minutes.

6. Other feedback relevant to this resource: Clarify the review category for primary cells and what likelihood of contamination requires full committee review. Primary human cells and tissues are already regulated under the OSHA Bloodborne Pathogens Standard, therefore requiring full committee review for these materials adds an additional burden for IBC members. NIH should allow delegated review for primary human cells handled under universal precautions and applicable bloodborne-pathogen requirements and when primary cells may contain a RG2 agent, consistent with the delegated-review pathway for work conducted directly with wild-type RG2 biological agents. Full committee review should be reserved for primary cells known or reasonably suspected to contain a RG3 or RG4 agent.

476. Stanford

I am responding: On behalf of myself

Name:

Name of Organization: Stanford

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Medical microbiology and immunology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The new policy language would reclassify any nucleic acid that “can be transcribed or translated”, including most transiently introduced transfected plasmids, exogenous mRNAs, and several vaccine technologies as a "genetic modification." This is a fundamental error. This re-classification could lead to confusion, misunderstanding, and loss of public trust in routine RNA research and in recombinant vaccine technologies, with potentially devastating public health outcomes.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

477. Frank Sangiorgi

I am responding: On behalf of myself

Name: Frank Sangiorgi

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Neurobiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Title suggests a policy designed to promote an overarching view of biosafety, yet the Scope states that the Policy is tied to human health (e.g., "biomedical research in laboratory settings, involving biohazards"). A definition of "biohazard" is not provided in the General Definitions Section, yet the "National Biosafety Data and Safety Analysis Center is included. Furthermore, the Scope excludes plants, animals, and the environment, yet mention of animals and the environment appear later in the document, especially with respect to the prion definition being extended to both humans and animals. The gap between biosafety involving humans and biosafety concerned with animals and plants can be addressed by either limiting the new Policy to human health concerns, or by establishing collaborative connections to other federal agencies that will address hazards to animals and the environment.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Within the proposed oversight tiers (Section IV), there is overlap between Section IV-2 and Section IV-3 with regard to wild-type Risk Group (RG) biological agents. In addition, Section IV-3 places all transgenic organisms at BSL1/ABSL1 under IBC review and approval. Again, there is no definition of a transgenic organism, and the sentence may be construed to cover transgenic animals derived from agricultural animals and non-human primates. The majority of transgenic rodents do not present any severe biosafety risk, and are indeed exempt from the current NIH Guidelines. In the case of the broad term "transgenic organisms" then a risk assessment would be beneficial. While the use of Risk Groups are useful, and promoted in Section V-A as being harmonized with the BMBL 6th edition, the evaluation of transgenic organisms requires more information. The risk assessment of transgenic organisms would include a more comprehensive approach, including information of the experimental procedures used, the nature of the transgene (transcription factor vs structural protein-coding gene), along with the equipment available and even the expertise and knowledge of the researchers conducting the work. This type of assessment is the exact system that was promoted in the Listening Session for the Biosafety Modernization Initiative, and may lead the exemption of many transgenic animal models from NIH review.

3. Continued utility of Risk Groups: The use of Risk Groups as a baseline for risk assessment is generally appropriate when evaluating the particular biological agent for use as is, and when being considered for

genetic manipulation. However, as noted above in the response to Section IV-3 of the Policy, such an assessment would benefit from the considering the methods used in the experimental manipulation, the equipment used and the appropriateness of the physical and biological containment, and the knowledge and expertise of the individuals performing the research. Again, the opening call by the NIH Modernization Initiative for a risk-based Policy would benefit greatly by simply expanding from Risk Groups to the consideration of additional factors (as described in Section II-A-3 of the current NIH Guidelines) involved in a laboratory's research.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The mechanism to encourage and accommodate voluntary compliance by non-NIH funded institutions should mirror the current NIH Guidelines Section IV-D, with the overall approach that the NIH is a knowledgeable partner and willing to support research in any research institution that would reach out for assistance and review.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The Draft Incident Report Template does not distinguish between lower risk incidents (e.g., an animal scratch) versus higher risk incidents (e.g., the laboratory release of an RG3 microorganism). The reporting of higher risk incidents may be more instructive for many institutions looking for examples of certain incidents and the practices that were used in resolving those situations. Along with this idea of a "teaching moment", the template could use more flexibility in reporting, as not every institution is identical, and the inclusion of the principal investigator's name does not add any additional actionable information to the Report.

The Draft Meeting Minutes Template should not allow for the public disclosure of the principal investigator's name, institutional project numbers, sensitive animal research information, proprietary material and research results, and other details the would compromise the safety and security of the institution, institutional staff, and research personnel. That such information would be available not only to NIH but to other individuals, including any potential malicious actors, is presumably not the outcome that the work toward transparency was meant to achieve.

6. Other feedback relevant to this resource: Due to the changes suggested by this Policy, and in the furtherance of co-ordination between this Policy and the new DGOF and IROC Policy (particularly in terms of the attestations and addition information that are required by both Policies), a careful revision of the NIH Policy to address the points of contact with DGOF/IROC (such as experimental risk evaluations) would be beneficial. Perhaps a phased application of the new NIH Policy would allow universities and other institutions to conduct appropriate risk assessments and attestations and have those documents approved without interrupting the research presently being conducted.

478. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy needs to clearly define terms so institutions can implement it as required. Any definition lists are very vague and some are missing altogether, such as GDMO. This is also needed that variety institutions can implement it consistently!

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): NIH should require limited preapproval requirements for high risk research or genuinely novel constructs and allow local IBCs to use SME to assess basic research.

3. Continued utility of Risk Groups: Research institutions need to have the flexibility to regulate low risk research depending on their specific risk tolerance, which depends on many factors.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Incident reporting should include standard de-identified summaries and redacted information to comply with HIPAA requirements.

There's needs to be clear federal thresholds that preserve confidential reporting. Management of low risk incidents should remain with local oversight.

6. Other feedback relevant to this resource: There needs to be a minimum 24-month transition phase to update programs and implement as needed.

479. Edwin Siu

I am responding: On behalf of myself

Name: Edwin Siu

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: biosafety officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): biomedical sciences

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The definitions of biohazards that fall under oversight are not well delineated leading to an excessively broad scope for oversight, especially for genetic modification. I do not have an issue with the first definition, given as "The introduction into cells, organisms, or viruses of nucleic acid molecules that meet any of the following criteria: Possess biological properties that enable introduction of stable alterations (e.g., mutations, insertions, or deletions) into the genome (e.g., cis elements involved in integration, gene editing); or Have the potential for one or more cycles of replication in a cell; or Can be transcribed or translated." This definition is easy to interpret and apply because it matches our current understanding and expectations of what activities constitute genetic modification.

The excessive scope in oversight is due to the second definition which includes "the introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means". Most of these named "means" represent causal mechanisms by which natural genetic variation can arise in reproducing organisms. For example, reassortment is a typical phenomenon observed in sexual reproduction and it generates genetic variation among offspring even when they are progeny of the same parents. Natural selection is only possible when there is a range of heritable and varied traits present in a population. A trait is heritable because the genetic variation that underpins it is the product of stable alterations to the genome. This second definition of genetic modification thus captures nearly all the natural genetic variation upon which natural selection occurs.

If our focus is on systematic and directed efforts at genetic modification, it is not sufficient to merely list processes that produce stable alterations to the genome. Further qualifiers are needed in this second definition, unless we want to start doing risk assessments for every mouse colony and flasks of cells. The second definition unnecessarily stretches the meaning of genetic modification to the point where it is now cumbersome to use.

The introduction of fluorescent marker into a flask of cells via molecular biology techniques is a relatively

undisputed example of genetic modification and that is captured by the first definition of genetic modification. However, our fluorescent marker won't be present in every single cell in the flask after this activity and if the heterogenous population of cells continues to reproduce it might jeopardize the stability of our alteration. Subsequently, we sort the already genetically modified cells for our fluorescent marker and retain only the cells with the fluorescence for continued cultivation, ensuring stable alterations through passaging. This would qualify as a second act of genetic modification under the second definition. However, in practice we are only interested in considered the risk of the first activity, because the passaging activity seems too trivial to evaluate for risk and is comparable to selective breeding of mice.

Leaving the second definition of genetic modification as-is will lead to requiring additional oversight of low risk and inconsequential activities that are ordinary natural events for cell culture and animal breeding. Given the mostly justifiable expansion of scope in oversight developed elsewhere in the draft policy on topics, this second definition of genetic modification seems like an unwise area to spend our attention and resources.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Biosafety officer should be more clearly defined in the policy to illustrate the type of competencies needed.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The current level of details requested on the required incident reporting template, if required to be publicly posted, will compromise the ability of institutions to maintain cooperation and open communication with investigators. The public facing report should be more limited in the information required to be published because details in the template (even with redaction) could allow the identification of individual parties due to the truly unique nature of research activities and the limited number of people who conduct such work worldwide. The public posting could breach the privacy of affected individuals, identify targets for intellectual property theft, and expose protected health information.

Researchers and investigators who believe they are negatively affected by public posting of the incident reports may become discouraged to file initial reports or cooperate by sharing incident details. Therefore, I think the publicly posted incident report template should be a different form from the NIH-bound reporting template.

6. Other feedback relevant to this resource: N/A

480. Cheryl Flynn, MD

I am responding: On behalf of myself

Name: Cheryl Flynn, MD

Name of Organization: Mount Holyoke College

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): I am the medical/clinical member of our Institutional Biosafety Committee that reviews all research projects done by faculty involving

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: seems a bit over-reaching to me;

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I appreciate the opportunity to have delegated review. My read on these proposed changes is that all delegated reviews must get full committee approval anyway.

so perhaps instead of the full committee approval, it could be a report out of delegated review team and include "approved" research still in the minutes of the meeting for public reporting but not a formal full committee approval (which, in my opinion, would require me to review the entire research application, which seems at odds with the option of creating delegated review...).

3. Continued utility of Risk Groups: I'm unclear why the change is necessary; changing language if indeed it simplifies things is OK but researchers are quite attuned to the BSL language/categories now.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I support the requirement of incident reporting; but I do not support the public display of each and every incident. Requiring the detailed level of reporting for minor injuries in the lab is not a helpful use of staff or faculty time; further, publication of each event will seem like labs are unsafe simply due to the nature of students working with animals.

I would suggest requiring the reporting of all incidents; detail required on those of significance; and reporting in aggregate but by category of severity of incident.
much like in medicine, people will stop reporting errors/incidents if there if fault to be found and then we miss the opportunity to improve.
+++

the meeting minutes template is OK but requires much more detail for unclear benefit than the current format our institution uses.
I think there can be a more balanced approach to safety via public sharing of details and the appropriate confidentiality of researchers

6. Other feedback relevant to this resource: N/A

481. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): BSL-3, Select Agents, BSL-2, rsNA, IBC etc

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached

3. Continued utility of Risk Groups: See attached.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): This new policy will make it even more difficult to encourage voluntary compliance due to its' complexity and increased scope.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached

6. Other feedback relevant to this resource: See attached

Uploaded File: Draft-NIH-Biosafety-Policy-Comments_101926v7.docx

Description: Comments on NIH Draft Biosafety Policy

October 19, 2026

To NIH OSP,

Thank you for the opportunity to provide comments on the Draft NIH Biosafety Policy for Research Involving Biohazards. These comments are submitted from the perspective of an Institutional Biosafety Committee (IBC), at an academic research institution with extensive experience administering complex biosafety, laboratory safety, and regulatory compliance programs.

General Comments

Theme	Recommendation
1. **Scope and definitions**	Narrow the definitions of genetic modification and primary cells. Remove cell passaging, chemical mutagenesis, and radiation from IBC scope. Recognize existing occupational-health mechanisms for primary cell work.
2. **IBC Membership**	NIH should provide additional implementation guidance regarding public member recruitment, protection of personal information, and management of security concerns.
3. **Incident Reporting and Transparency**	In the interest of transparency, the NIH could instead post aggregate/de-identified reporting information together with incident responses (both Institutional and NIH/Oversight Agencies) annually. Narrow the NIH-reportable threshold to risk-relevant events. The new Policy opens the entity and its personnel to additional safety risks. This

	step to increase transparency may further endanger those who are doing research.
4. **Registration Cycle**	Replace the three-year de novo registration with a five-year cycle or risk-based intervals, retaining substantive annual review.
5. **Exemptions**	Carry the NIH Guidelines exemptions forward, including Appendix C and the rodent breeding and purchase exemption; state the Risk Group 1 exemption plainly.
6. **Biosafety Professional**	Requiring a biosafety professional only at BSL-3, BSL-4, and for gene drive research undercuts risk-based framing and permits delegation to unqualified personnel.
7. **Implementation Guidance**	Provide implementation guidance to increase consistency.

Specific Comments

1. Scope of the Policy

Recommendation

NIH should further clarify which activities are intended to be within scope and provide examples. Also, the NIH Guidelines contain where risk got defined. Institutions looked to them for Risk Group classification. If that reference disappears, it is unclear what institutions are meant to use in their place.

a. NIH should provide a detailed scope matrix that includes common examples of research activities that are in scope, out of scope, and conditionally in scope. This matrix should include work involving human specimens, RG1 organisms, environmental samples, microbiome studies, inactivated materials, plant pathogens, toxins (including nonpeptidic biological toxins), gene therapy products, viral vector-based genome screening libraries, and synthetic biology research. Such clarification would promote consistent

implementation across institutions and reduce variability in local interpretation.

i. “Toxins" need to be better defined. For example, limiting oversight to toxins that are proteins/peptides excludes toxins like tetrodotoxin or T-2 on the SA list. A specific list of toxins for which oversight is needed should be provided. This matrix should provide guidance for appropriate biosafety measures.

b. The Scope of the Draft Policy expands beyond recombinant nucleic acid research to cover emerging biotechnology research, but institutions require examples of such NIH biosafety policy coverage.

Rationale

Ambiguity may result in inconsistent implementation among institutions.

2. IBC Membership and Public Transparency

Recommendation

NIH should provide additional implementation guidance regarding public member recruitment, protection of personal information, and management of security concerns.

Rationale

Many institutions have faced sustained harassment, threats, legal action, and risks to the personal safety of individuals involved in research and or research oversight. These requirements are likely to intensify these challenges.

3. Incident Reporting

Recommendation

NIH should maintain similar reporting requirements and not require publicly posting incident reports. As stated above, providing information regarding the institution, its research, the animals used in that research, etc., opens the entity and its personnel to additional risks to safety. This requirement will not increase transparency; it will further endanger those doing research and making a difference. NIH should continue to monitor and review all incidents covered under the policy and not require that they be publicly

posted. In the interest of transparency, the NIH could instead post aggregate/de-identified reporting information together with incident responses (both Institutional and NIH) annually.

Rationale

Providing incident reports to the public will not help to provide transparency it will only increase the risk for threats and harassment to the institution while jeopardizing personal safety. This requirement may have the opposite intended effect and Principal Investigators may not report incidents for fear of public scrutiny or harassment.

4. Registration Cycle

Recommendation

Replace the proposed three-year de novo registration requirement with a five-year renewal cycle, while retaining annual investigator attestations and reviewing substantive protocol changes.

Rationale

For low-risk research that remains subject to registration, a five-year renewal cycle would reduce unnecessary administrative workload while preserving institutional awareness of ongoing activities. Annual attestations, amendment review for significant changes, incident reporting, laboratory inspections, and training requirements would continue to provide effective oversight and opportunities to identify changes that may alter the biosafety risk assessment. A longer renewal interval would allow IBCs and biosafety programs to devote more time and resources to higher-risk projects where detailed reviews provide the greatest benefit to personnel, public health, and the environment.

5. Exemptions

Recommendation

Create an exemption category or alternatively expand the scope of activities eligible for administrative registration without IBC review. Examples could include work with well-characterized cell lines, non-integrating and replication-incompetent vectors expressing low-risk transgenes, standard molecular biology experiments involving nonpathogenic agents, and other research with well-established biosafety profiles.

Rationale

The proposed policy significantly expands the scope of research subject to institutional oversight while eliminating the exemption framework that has historically allowed IBCs to focus resources on higher-risk research. As written, a substantial volume of low-risk, routinely conducted research would require either full IBC review or delegated review, increasing administrative burden for investigators, biosafety offices, and IBCs without a corresponding improvement in safety.

An exemption category would allow institutions to concentrate oversight on activities that present meaningful biosafety concerns, including work with Risk Group 2-4 agents, genetically modified organisms with uncertain risk profiles, emerging agents, and other higher-risk research. Such a risk-based approach is consistent with the stated goal of reducing administrative burden for low-risk research while strengthening oversight where it is most needed.

6. Biosafety Professional

Recommendation

The draft Policy states, “A BSO must be appointed when the institution conducts research subject to the Policy i) at BSL-3 or 4, or ii) involving GDMOs.” NIH should require that all institutions maintaining an Institutional Biosafety Committee (IBC) appoint a qualified Biosafety Officer or Biosafety Professional as a voting member of the IBC, regardless of the institution's current research portfolio.

Rationale

The IBC and BSO function most effectively as complementary components of the institutional biosafety program. While the IBC provides multidisciplinary review, oversight, and risk-based decision making, the BSO provides the day-to-day technical expertise, operational awareness, and implementation support necessary to ensure that biosafety practices are effectively applied throughout the institution.

Many institutions conduct research that is classified as lower risk under the proposed policy yet still involves complex biological agents, recombinant or synthetic nucleic acids, human materials, viral vectors, toxins, or emerging technologies that benefit from professional biosafety risk assessment and oversight. Requiring a BSO only when BSL-3/4 research or GDMOs are present creates an artificial threshold that may leave institutions without dedicated biosafety expertise despite maintaining active IBC programs.

A qualified biosafety professional provides continuity between IBC meetings by assisting investigators with risk assessments, evaluating containment strategies, conducting laboratory inspections, supporting incident investigations, monitoring compliance with IBC approvals, providing training, and serving as a resource to researchers and institutional leadership. These activities strengthen biosafety culture and improve the quality and consistency of IBC reviews.

In addition, the draft policy substantially expands the scope of oversight beyond recombinant and synthetic nucleic acid research to encompass a broad range of biohazards. As institutional responsibilities increase, the need for professional biosafety expertise likewise increases. Requiring a BSO for all institutions with an IBC would promote consistent implementation of the policy, improve institutional compliance, and enhance the safe conduct of research across the biomedical enterprise.

7. Implementation Guidance

Recommendation

NIH should develop:

- Frequently Asked Questions
- Decision trees
- Risk categorization examples
- Model SOPs
- Training modules
- Example IBC review documentation

Rationale

These resources would promote consistent implementation across the research enterprise.

Conclusion

NIH's efforts to modernize biosafety oversight and support the development of a unified, risk-based framework that promotes the safe and responsible conduct of research involving biohazards, are appreciated. The draft Policy represents an important opportunity to strengthen biosafety oversight while providing clarity and consistency across the research enterprise.

As drafted, however, several provisions may unintentionally expand oversight of lower-risk activities, increase administrative burden, and create implementation challenges without providing a commensurate improvement in biosafety outcomes. In particular, clearer definitions, preservation of appropriate exemptions, meaningful implementation guidance, and greater flexibility in registration and reporting requirements would help ensure that institutional resources remain focused on activities that present the most significant biosafety risks.

We also encourage NIH to carefully consider the potential unintended consequences of public incident reporting and other transparency provisions that may increase risks to researchers, biosafety professionals, IBC members, and institutions. Transparency is an important objective, but it should be achieved in a manner that promotes accountability without compromising personal safety, security, or the open reporting culture that is essential to effective biosafety programs.

Finally, successful implementation of the Policy will depend on the availability of clear guidance, practical tools, and sufficient institutional expertise. Providing FAQs, decision trees, examples, and other implementation resources will help foster consistent interpretation and application of the Policy across institutions of varying size and complexity.

We respectfully encourage NIH to incorporate these recommendations as it refines the final Policy. Doing so will help ensure that the framework remains science-based, risk-informed, practical to implement, and effective at advancing biosafety while supporting the continued success of the biomedical research enterprise. Thank you for the opportunity to provide these comments and for NIH's continued leadership in promoting biosafety and responsible research practices.

482. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: In general, I like the unification of oversight for all research involving biohazards, whether or not such research involves recombinant or synthetic nucleic acid technology. It is a positive change which supports a more comprehensive and cohesive institutional biosafety program. However, there are areas where I believe the draft goes to far and will result in overly burdensome requirements for very low risk activities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The addition of a Delegated Review mechanism is another positive change. It should reduce the burden on IBCs, while providing institutions with the flexibility to define the Delegated Review process in a way that ensures appropriate oversight of lower-risk activities at individual institutions.

3. Continued utility of Risk Groups: I agree using Risk Groups as a baseline for risk assessment is appropriate. However, biosafety levels are also an important consideration.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: New incident reporting requirements have an expanded scope of what counts as an incident in addition to the requirement to post all incident reports on a public website.
a. Impact: These changes are expected to have a significant negative impact. The trust that biosafety programs have built up over the years in supporting researchers and encouraging people to report accidents will be eroded by fear of negative ramifications and/or retaliatory action. Even if reporting is anonymized and only a PI or supervisor name is included in the published report, there is a perceived risk of that information being used against the person, lab, and/or institution. People will be less likely to report accidents, which increases the risks associated with untreated injuries or exposures to hazardous materials.
b. Recommendation 1: Individual incident reports should not be publicly posted. Reporting should be to NIH, where data on incidents can be aggregated and trends analyzed and/or reported in a way that removes institutional affiliation to further anonymize individuals involved in an incident. That allows for

analysis of the data and identification of trends, which would be a valuable resource to the community, while avoiding negative consequences on the individual, lab, or institution, which would, in turn, undermine the value of the incident reporting process.
c. Recommendation 2: If institutions must be required to publicly post incident information, allow an aggregated annual report. Such an approach could be modeled after OSHA's Form 300A (Summary of Work-Related Injuries and Illnesses). We would strongly recommend this approach for incidents defined by this Policy, which would not be reported to NIH but would be reported to the IBC.

6. Other feedback relevant to this resource: I greatly appreciate the outreach and request for feedback that NIH has made with regard to updating this policy.

Uploaded File: Comments-on-proposed-NIH-Biosafety-Policy-Updates.docx

Description: Attached are comments that were circulated, reviewed, and generally approved by a broad group of Biosafety Professionals.

Comments on the proposed updates to the NIH Biosafety Policy:

In general, we like the unification of oversight for all research involving biohazards, whether or not such research involves recombinant or synthetic nucleic acid technology. It is a positive change which supports a more comprehensive and cohesive institutional biosafety program. The addition of a Delegated Review mechanism is another positive change. It should reduce the burden on IBCs, while providing institutions with the flexibility to define the Delegated Review process in a way that ensures appropriate oversight of lower-risk activities at individual institutions. We support these notable policy improvements.

While many aspects of the draft Policy represent improvements, there are several changes that are likely to have significant negative consequences, as well as points that would benefit from clarification. We respectfully submit the comments below for consideration to further improve the Policy.

New incident reporting requirements have an expanded scope of what counts as an incident in addition to the requirement to post all incident reports on a public website.

a. **Impact:** These changes are expected to have a significant negative impact. The trust that biosafety programs have built up over the years in supporting researchers and encouraging people to report accidents will be eroded by fear of negative ramifications and/or retaliatory action. Even if reporting is anonymized and only a PI or supervisor name is included in the published report, there is a perceived risk of that information being used against the person, lab, and/or institution. People will be less likely to report accidents, which increases the risks associated with untreated injuries or exposures to hazardous materials.

b. **Recommendation 1**: Individual incident reports should not be publicly posted. Reporting should be to NIH, where data on incidents can be aggregated and trends analyzed and/or reported in a way that removes institutional affiliation to further anonymize individuals involved in an incident. That allows for analysis of the data and identification of trends, which would be a valuable resource to the community, while avoiding negative consequences on the individual, lab, or institution, which would, in turn, undermine the value of the incident reporting process.

c. **Recommendation 2**: If institutions must be required to publicly post incident information, allow an aggregated annual report. Such an approach could be modeled after OSHA's Form 300A (Summary of Work-Related Injuries and Illnesses). We would strongly recommend this approach for incidents defined by this Policy, which would not be reported to NIH but would be reported to the IBC.

2. The draft Policy states that IBC approval should be granted for a period not to exceed three years, at which time a de novo registration submission and review is required. It further lists failure to maintain IBC approval as a reportable incident.

    a. **Impact:** The expected impacts of these changes are a significantly increased administrative burden and unintentional non-compliance. In the absence of a specified term limit, many institutions adopted internal policies that require IBC approval to be renewed within a 5-year period, which also coincides with the length of many grants supporting the approved research activities. Switching to a shorter 3-year renewal cycle presents a significant increase in committee workload. Additionally, well-intentioned PIs may face unexpected emergencies, or their registration renewal may come at a time when they are burdened with high workloads from teaching and/or other institutional responsibilities. Because there is no mechanism described in the draft Policy for allowing extensions to PIs facing extenuating circumstances, failure to renew an IBC registration on time would result in a reportable incident of non-compliance.

    b. **Recommendation 1:** Keep a defined term limit on IBC approval but increase the term of IBC approval to 5 years.

    c. **Recommendation 2:** Empower IBCs to exercise judgement and flexibility in granting reasonable, one-time extensions to PIs facing extenuating circumstances and/or moving a registration renewal to a different time of year so as not to conflict with other high-workload periods.

3. The draft Policy states that research with primary cells that may be contaminated by adventitious agents requires IBC review and approval under Section IV-2. We interpret this new scope to mean that any primary human cell line, tissue, or clinical specimen with an unknown status (has not been tested for bloodborne pathogens or other infectious agents) will have to go to the IBC for approval, whereas none of this material required IBC review previously. Instead, this material fell under the OSHA Bloodborne Pathogens Standard, which requires institutions to establish oversight mechanisms that have worked for many decades.

    a. **Impact**: This change is expected to have a significant negative impact. The increased burden on most IBCs will be enormous, with no apparent benefit, since the existing mechanisms to comply with the OSHA Bloodborne Pathogens Standard must still be maintained. This is an unnecessary duplication of oversight, and the increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation**: Allow this type of material to be approved via the new Delegated Review process described in Section IV-3 rather than requiring IBC

review. That would allow institutions flexibility to integrate existing biosafety oversight mechanisms into the Delegated Review process defined by the new Policy.

4. The draft Policy states that research involving genetically modified cells, viruses, or organisms, other than plants requires IBC approval and approval under Section IV-2. Previously, a large portion of genetically modified cell lines were considered exempt under Section III-F-8, Appendix C-I. For many IBCs, that type of material made up the majority of genetically modified material, and because it was considered exempt and did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely and in accordance with the OSHA Bloodborne Pathogens Standard. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8, Appendix C-I now falls under Section IV-2 and requires full committee review.

    a. **Impact**: This change is expected to have a <u>significant negative impact</u>. This will create an enormous new burden on IBCs, with no apparent benefit because the main risk associated with material that fell under Section III-F-8, Appendix C-I was the risk of adventitious agents or bloodborne pathogens, as mentioned in point 3 above. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation**: Retain the Section III-F-8, Appendix C-I exemption, or allow materials that would have fallen under Section III-F-8, Appendix C-I to be approved via the Delegated Review process described in Section IV-3.

5. The draft Policy's definition of a genetic modification includes introduction into cells, organisms, or viruses of stable alterations into the genome by passaging. It is not clear what passaging activity falls within the Policy scope. Simply culturing an organism in vitro will lead to accumulation of undefined genetic alterations and could be considered passaging. Cultures that are maintained in a lab are also considered to be passaged through the process of sub-culturing to create multiple stocks from an original sample. Further, most of the time, growing an organism in vitro or in a model system selects for mutations that optimize growth in a lab environment, not in a human host, and these lab-adapted strains typically lose virulence or pathogenicity. The Influenza A/Puerto Rico/8/1934 (H1N1) strain (often called PR8 influenza) is a classic, mouse-adapted laboratory strain of the influenza A virus isolated from a human patient in Puerto Rico in 1934. It is an example of a strain that is a lower risk option for studying influenza. These examples of passaging generally have not required IBC review. In the draft Policy, all of these activities would require IBC review and approval under Section IV-2 (see also point 4 above).

a. **Impact**: The current definition of genetic modification is expected to have a significant negative impact. This will create an enormous new burden on IBCs, with no apparent benefit because most passaging does not increase the risk of the agent or associated research activities. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

b. **Recommendation**: We recommend refining the scope of the definition of genetic modifications by defining passaging as the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile. Examples of passaging activities that should be included in Section IV-2 include passaging with the intent or likelihood for an agent to acquire a new virulence trait or antibiotic resistance or to adapt a pathogen to a new host species and/or tissue tropism.

6. In the draft Policy, the definition of genetic modification that falls within the scope of the policy now includes modification via chemical or radiological means. Further, the draft Policy requires the IBC to review all genetically modified cells under Section IV-2 (see also point 4 above). The main risk associated with use of chemical or radiological agents to create mutations is in the handling of the chemical or radiological material, not necessarily in handling the cells once the mutagen has been removed. There are separate regulations that apply to chemical and radiological hazards. The use of chemical and radiological hazards is best handled by the respective safety experts who are familiar with the appropriate regulations and safety requirements, not the IBC. Assessment of the risks of these mutagens are outside of the scope of an IBC, since IBC members typically have little to no expertise on chemical or radiological hazards.

    a. **Impact**: This is a vast expansion of scope that will duplicate oversight and increase burden on IBCs, without a clear benefit. Further, the IBCs typically lack appropriate expertise for evaluating the risks associated with these mutagens. The increased burden on IBCs will detract attention from higher-risk matters, which do fall within the expertise of the committee.

    b. **Recommendation**: Remove chemical and radiological means from the definition of genetic modifications that fall within the scope of the policy and defer oversight to existing regulations that apply to the use of chemical and radiological hazards. Alternatively, refine the scope to apply to experiments in which the mutagenic agent is combined with the deliberate culturing of an organism under a selective pressure that could reasonably be expected to lead to an organism with a higher-risk profile, as recommended for passaging in point 5 above.

7. The draft policy states that research with genetically modified RG1 biological agents requires Delegated Review under Section IV-3. Previously, most standard cloning and/or

protein expression with *E. coli* and other model host-vector systems were considered exempt under Section III-F-8, and it did not require any level of review. Many institutions have adopted internal review and approval mechanisms as a safeguard to make sure those materials really were exempt and were still being handled safely with proper waste disposal procedures. In the draft Policy, there is no carve-out for exempted materials, so everything that previously fell under Section III-F-8 now requires Delegated Review.

a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. The increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

b. **Recommendation 1**: We strongly recommend retaining existing III-F-1 through III-F-8 exemptions.

c. **Recommendation 2**: Furthermore, and supported by decades of safe research experience, we also recommend expanding the exemptions to include other low-risk cloning and protein expression research in model organisms such as *E. coli* BL21 strains, *C. elegans*, and *Drosophila*.

8. The draft Policy states that research conducted with transgenic organisms at BSL-1/ABSL-1" requires Delegated Review. Previously, almost all breeding or purchasing of transgenic rodents was exempt under Section III-F-8, Appendix C-VII and was not typically registered with an IBC at all. Instead, oversight of those transgenic rodents typically has been handled through federally mandated Institutional Animal Care and Use Committees (IACUCs) that have biosafety professionals as members who conduct risk assessments and suggest risk mitigation measures as part of that review process. Many IBCs do not even have a mechanism for tracking this information. Additionally, many researchers using transgenic mice are not using any other sort of biological material; the research is often focused on behavioral studies or pre-clinical studies that fall outside the scope of an IBC. A very large proportion of transgenic animal work is done with transgenic rodents and zebrafish, and almost all of that work poses no new risk compared to the unmodified rodents and zebrafish.

    a. **Impact**: This will be an enormous new burden on IBCs and/or Biosafety programs that do not already have internal biosafety oversight mechanisms for reviewing this work, with no apparent benefit. Again, the increased burden on IBCs and Biosafety staff will detract attention from higher-risk matters.

    b. **Recommendation 1**: We strongly recommend retaining the III-F-8, Appendix C-VII exemption and allow existing oversight of these low-risk animals to continue via the IACUC.

c. **Recommendation 2**: As mentioned in point 7 above, we also recommend expanding the exemptions to include other low-risk transgenic model organisms such as zebrafish, *C. elegans* and *Drosophila*.

9. The draft Policy defines biological agents that fall within the scope as bacteria, viruses, fungi, or parasites that cause human disease. This definition seems to contradict the draft Policy's requirement for Delegated Review of research with genetically modified RG1 biological agents (see point 7 above). Risk Group 1 agents are <u>not</u> associated with disease in healthy adult humans. Some agents may be considered opportunistic pathogens, but there is currently no list of RG1 organisms that are considered opportunistic pathogens.

    a. **Recommendation 1:** NIH should clarify the nature of biological agents that fall within the scope of the Policy. We recommend that the Policy scope is limited to pathogenic biological agents that cause disease in humans, including opportunistic pathogens but <u>excluding</u> non-pathogenic agents.

    b. **Recommendation 2**: As there is no list of RG1 agents, and the list of RG2 agents is incomplete, we further recommend empowering the IBCs, Biosafety programs, and PIs to make the determination of RG1 and RG2 for biological agents that are not currently listed in Appendix B of the NIH Guidelines or the BMBL using the risk assessment guidance provided therein.

10. The draft Policy's definition of a genetic modification includes introduction of materials that can be transcribed or translated. This would include materials such as purified or synthetic miRNAs, snRNAs, shRNAs, and mRNAs, which are transient in nature and may lead to changes in gene expression but do not replicate and do not modify or integrate into the genome. Work with such materials was previously exempted under III-F-1 but would now fall under Section IV-2 and require IBC review and approval.

    a. **Impact**: The current definition of genetic modification is expected to have a <u>significant negative impact</u>. This will create a significant new burden on IBCs, with no apparent benefit given that no genetic modifications are made with these materials. The increased burden on IBCs will detract attention from higher-risk matters that deserve IBC attention.

    b. **Recommendation:** We recommend retaining the III-F-1 exemption and removing these materials from the scope of the Policy.

11. The scope of the draft Policy includes prions and self-aggregating proteins, and research activities involving these materials would require IBC review and approval. We support the draft Policy as it pertains to prions, but request refinement of the oversight pertaining to self-aggregating proteins. IBC oversight should not extend automatically to every protein capable of self-aggregation. Protein aggregation is common in biology and,

by itself, does not establish an infectious or exposure hazard. Oversight should instead focus on proteins or protein assemblies for which there is credible evidence that an aggregated conformer can act as a persistent, self-propagating seed; induce conformational conversion of the corresponding native protein; spread between cells or tissues; and transmit pathology following experimental exposure or inoculation. We recommend the following risk-assessment approach, which is consistent with the BMBL principle that containment decisions should be protocol-driven rather than based only on an agent's name.

a. **Recommendation 1:** Classical mammalian prions and prion-containing tissues should remain categorically within IBC purview because of their established infectivity, potential for serious disease, environmental persistence, and resistance to conventional inactivation procedures.

b. **Recommendation 2:** Seed-competent aggregates of α-synuclein, including preformed fibrils, amplified seeds, and α-synuclein-containing material derived from affected human or animal tissue, should also be subject to IBC review because α-synuclein assemblies have demonstrated prion-like templating, cellular and anatomical propagation, and experimental transmissibility in animal models. Inclusion under IBC oversight should not be understood to mean that α-synuclein is known to be naturally communicable between people or that it presents the same level of hazard as a classical prion.

c. **Recommendation 3:** Other self-aggregating proteins should be evaluated individually rather than be included in Section IV-2 of the draft Policy solely because they form oligomers, fibrils, or amyloid. Relevant considerations should include evidence of experimentally transmissible pathology, persistence of seeding activity, resistance to standard decontamination, source and concentration of the material, route and scale of exposure, use of human- or animal-derived pathological tissue, and procedures involving inoculation, sharps, aerosols, or other opportunities for occupational exposure. Routine work with non-seed-competent monomeric proteins or aggregates lacking evidence of biological propagation would not ordinarily require specialized biosafety review beyond the requirements otherwise applicable to the experimental system, and we recommend that the Delegated Review mechanism described in Section IV-3 be applied to such work.

12. The scope of the draft Policy includes toxins listed as Select Agents, and research activities involving these materials would require IBC review and approval under Section IV-2, while research with biological toxin proteins not on the Select Agent list may be approved by Delegated Review under Section IV-3. We support this overall approach; however, we request refinement of the Policy with the following recommendations.

a. **Recommendation 1:** Allow research activities using exempt amounts of Select Agent toxins to be approved by Delegated Review. Most institutions have already developed effective internal biosafety oversight mechanisms for handling these exempted materials. Integrating those internal oversight mechanisms into the Delegated Review process would allow IBCs to focus on the higher-risk Select Agent work.

b. **Recommendation 2:** Either publish a list of biological toxins that fall within the scope of the Policy or use a threshold toxicity value as a risk-based factor for determining whether a biological toxin requires oversight by the Policy. We further recommend that biological toxins that have an LD_{50} greater than 1000 µg/kg be exempt from this Policy.

13. The scope of the draft Policy includes cells, viruses, or organisms, other than plants, that have been genetically modified. It is assumed that animals are included as organisms, but it is not clear what is considered an animal under this Policy.

    a. **Recommendation:** Use a definition of animal that is consistent with the Guide for the Care and Use of Laboratory Animals, which has been adopted by the NIH Office of Laboratory Animal Welfare, and which defines animals as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching.

14. The draft Policy indicates that the effective date will be 6 months from publication of final Policy, and that applicability includes ongoing work. It is unclear how ongoing work will be impacted by the new review and approval requirements. Work that was not subject to IBC oversight according to the NIH Guidelines may have been approved via voluntary institutional biosafety oversight mechanisms.

    a. **Impact:** Work that was approved by a Biosafety Officer (or other institutional biosafety oversight) and now requires a higher level of review by the IBC would need to cease until IBC approval is obtained. This would have a significant negative impact on a large number of projects that are suddenly subject to new oversight, thereby wasting grant money and setting back important research projects.

    b. **Recommendation:** Require activities that have not received approval by a Biosafety Officer or other institutional biosafety oversight mechanism to be reviewed and approved according to the final Policy within 6 months of the publication of the final Policy. For activities that have received approval by a Biosafety Officer or other institutional biosafety oversight mechanism, allow the existing approval to remain in place until such time as de novo registration is

required (see point 2 regarding our recommendation to allow 5-year term limits for IBC registration approvals).

483. Rebecca Cederberg

I am responding: On behalf of myself

Name: Rebecca Cederberg

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Role - Other: biosafety

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I support the NIH's effort to strengthen biosafety oversight and have a risk-based approach to mitigating safety hazards associated with biological research. However, the described scope and definitions lack details and examples and are confusing in regards to animal and plant pathogens; this is a missed opportunity to take a One Health approach for addressing research safety with biological materials. Plant pathogens appear to not be covered in the new policy, but biomedical researchers have evaluated plant and animal viruses as vaccine candidates, would this use of a plant pathogen be covered under this policy, but not the use of a plant virus to generate a genetically modified plant? Implementation guidance is needed to clarify what materials/work are covered by the policy. Previously, there was some low-risk work with r/sNA that was exempted from the NIH Guidelines or could be initiated with notification to the IBC, now it would appear those exempt activities require review and approval before initiation. Are activities with r/sNA outside of a cell exempt under the new policy?
The 6-month implementation timeline is not reasonable given the large shift in scope from the NIH Guidelines. Most institutions will require additional personnel and resources to register the expanded number of research faculty.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Section III-D states that NIH will provide interpretation for cases in which the Policy does not specifically assign containment levels. There are many non-pathogenic environmental and commensal microorganisms that are not listed in the BMBL. It is not obvious when NIH must be contacted to set containment level of research with microorganisms not specifically listed in the BMBL (does the work fall within scope of this policy?) or what would be classified as novel work requiring NIH consultation. In the NIH Guidelines, the description of research activities has assisted local IBC's in assigning a level of risk to work with r/sNA that could be categorized into a guideline. If the description of research activities is no longer a starting point for a risk assessment of work, will NIH be providing resources to supplement the loss of the Section III and the appendices of the NIH Guidelines? Will NIH post determinations that have been made on behalf of other entities as a resource for other IBCs?

3. Continued utility of Risk Groups: There is often confusion about RG and how that impacts a containment level assignment for described work. While it is a good starting point in the risk assessment of a human pathogen, the lack of a corresponding assignment for plant and animal pathogens can be confusing for researchers. A unified, dynamic reference tool for microorganisms is needed.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Ideally, a policy for research involving biohazards would not live in a single federal agency or subject to funding status. A comprehensive policy done in conjunction with other federal agencies would provide better oversight and the ability to make compliance a requirement of working with regulated materials regardless of funding source.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: While I strongly support a national database of incidents and injuries, as this would be an invaluable learning tool for the research and safety community and I am incredibly concerned about the requirement to include names and all details about the agent and work. Some PI labs are small enough, that sharing the researcher name may allow external groups to identify the specific individuals that were injured. Additionally, sharing agent/work information may be counter to Federal Select Agent biosecurity requirements. It is a security concern to call out agent information, particularly when it may not provide useful information to prevent future incidents.

6. Other feedback relevant to this resource: The National Academies “Supporting Responsible Innovation of Synthetic Cells: Biosafety , Biosecurity, and Environmental Considerations” is a good resource for safety assessments of synthetic cell novel research https://www.nationalacademies.org/projects/DELS-BLS-22-12/publication/29325 .
Examples of covered materials and activities are needed to clarify how this policy removes red tape for low-risk research if previously exempt work (i.e., purchase and transfer of transgenic rodents) now requires registration and review.

484. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): High Containment Infectious Disease Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: While the conceptual goal is unified and biosafety architecture is commendable, the current draft contains several structural ambiguities, excessive expansion of institutional liability, unrealistic reporting timelines, and a lack of necessary implementation resources. If finalized without substantial structural revisions, the policy threatens to overwhelm Institutional Biosafety Committees (IBCs), creates compliance bottlenecks, and disproportionately penalize smaller institutions.
1. Ambiguity and Overbreadth in Scope and Definitions
Critique: The draft policy restricts its scope to “biohazards,” but strangely, it does not provide a clear, stand-alone definition of the term itself, but rather a descriptive checklist of materials and human-health risk criteria. Further, the inclusion of “toxins, prions, and other self-aggregating proteins” without rigid concentration, mass, or activity thresholds creates enormous regulatory gray zones. Routine biochemistry and structural biology labs working on common, non-pathogenic proteins or minuscule quantities of common biochemicals are in danger of being unknowingly caught up in heavy IBC oversight.
Recommendation: Add a precise, legally-clear definition of “biohazard” directly into Section II. Develop clear, quantitative criteria (e.g., specific mass limits for toxins or biological activity units) to exempt low risk protein and biochemical research from required review at high levels of containment.
2. Increased Administrative Burden
Critique: The policy states that if an institution receives any NIH funding for any purpose, then all biomedical research conducted at that institution must comply with the policy, whether or not the research is funded by NIH, private industry, state grants or institutional funds. Taking this requirement from recombinant molecules to all biohazards is a dramatic increase in compliance footprint. This will be an administrative and financial burden that will be impossible for smaller academic institutions, teaching hospitals, and research institutes with minimal NIH funding to handle.
Recommendation: a)Restrict the institution-wide compliance mandate to only high-consequence or high-risk research categories (e.g., BSL-3/4 agents or dual-use research of concern). b)Allow use of streamlined self-certifying or periodic audit structures in place of full protocol-by-protocol IBC reviews for low-risk (BSL-1/BSL-2) non-NIH-funded projects.

3. Other Risks not Included in this Draft Policy
Critique: The draft policy does not address plants, plant pathogens, animals, or animal pathogens. This creates a gap that requires additional oversight by other government agencies; a key area of concern brought forth in all listening sessions.
Recommendation: NIH should consider a One Health approach that involves collaboration across funding agencies to reduce administrative burden while providing adequate oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): No comments

3. Continued utility of Risk Groups: 1. Critique: Risk Group assignments have been removed from the NIH Guidelines and are not comprehensively provided in the BMBL.
Recommendation: NIH should provide a definitive source or clear criteria for assigning Risk Groups to non-recombinant agents. Without standardized Risk Group classifications, institutions may reach different conclusions for the same agent, reducing consistency across the research community.
2. Please provide the biosafety rationale and supporting evidence that prompted the inclusion of additional oversight requirements for research involving insect cell lines, non-human/NHP cell lines, and pathogens that are not capable of causing disease in humans, including immunocompromised individuals. Clarification of the specific risks, incident history, or emerging concerns that necessitate these requirements would help the research community understand the basis for the policy change and assess whether the proposed oversight is proportionate to the actual biosafety risk posed by these systems.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): No Comments.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: 1. The proposed definition of an incident appears overly inclusive and may capture events with minimal biosafety significance. A broad incident definition could result in unnecessary reporting requirements, diverting resources from investigating and addressing more consequential biosafety events.
Critique: The draft calls for aggressive reporting windows, such as requiring a 24-hour notice for incidents with potential human health risks. Draft templates threaten to lump serious breaches of containment in with minor “near-misses” inside the lab. Publicly posting the details on every minor, internally resolved anomaly will swamp IBCs with paperwork, encourage under-reporting due to fear of public exposure, and fill federal regulators with noise rather than actionable safety intelligence.
Recommendation: a)Identify critical safety breaches (to be reported to federal government within 24 hours) vs. minor anomalies/near-misses (to be internally root-cause analyzed and included in annual institutional reports). b) Promote voluntary, internal near-miss reporting with safe-harbor provisions to encourage a culture of safety, not a culture of compliance avoidance.
2. The level of detail requested per registration in the Draft Meeting Minutes Template is so onerous that it seems it would be easier to just attach copies of each entire registration. For instance, if no training concerns were discussed for a particular registration, why must every training for every listed personnel be included in the minutes? Shouldn’t the Project Overview just be the Lay Summary? If a single registration utilizes 10 agents, are we expected to list every agent and describe each agent’s characteristic, source, modification, experimental manipulation, etc.? Again, it would then just be easier to attach a PDF of the entire registration and write ‘See attached’ in the Template as this information is generally captured in detail within the IBC protocol itself.

3. If required to use the provided Template as proposed, the minutes will be one long continuous table of information. Posting a PDF version of minutes to a public-facing website requires adherence to ADA requirements for the document. Making tables that cross multiple pages ADA compliant is a challenging, adding significant administrative burden to the requirement of posting the minutes immediately after they are approved.
4. If incidents reported to the IBC committee are to be made public, what guidance will be provided on reporting procedures to ensure this reporting does not violate the security and biosafety oversight requirements outlined by the CDC and APHIS Federal Select Agent Program policies. Federal oversight is applied to these facilities due to the nature of the work conducted and the risks associated with this work. Public information would increase security risks for personnel working in these Select Agent facilities and increase potential attacks (cyber or physical) on these facilities, opening institutions to increased risks and increased security burdens.
5. The draft emphasizes public transparency and proposes public disclosure of approved lower-containment determinations/ approvals, incident reports, and meeting minutes. In an era where artificial intelligence and automated data-scraping tools can accumulate institutional information, research related public disclosure may create acute biosecurity vulnerabilities, physical security risks, and exposure of intellectual property. Recommendation: a) Establish clear redaction procedures and legal protections to ensure that confidential business information, personally identifiable information (PII), and sensitive details about facility infrastructure are protected before any documents are made publicly available. b) Ensure public transparency rules follow standard FOIA exemptions so that sensitive security plans and infrastructure details remain protected from public disclosure.

6. Other feedback relevant to this resource: 1. Refine the definition of a reportable incident and provide clearer thresholds for reporting to support a risk-based, consistent approach across institutions.
2. Provide a list of risk groups for all wild type pathogens that fall under the scope of the policy.
3. Provide a list of toxins that would fall under the scope of the policy.
4. We feel like there is an inadequate transition window and lack of federal resource support. The policy requires all existing and new awards to comply within six months of its final publication. This is a very short timeframe, considering that institutions will need to update their standard operating procedures, revise internal policies, modify electronic protocol management systems, and train hundreds of researchers. On top of these challenges, no federal grants or financial support are available to help institutions strengthen or expand their oversight programs within the Division of Research, Sponsored Programs, or Environmental Health and Safety (EHS) programs to meet the new requirements. Recommendation: a) Allow 12 to 24 months for institutions to meet the new requirements, using a gradual rollout that starts with a voluntary pilot program. b) Provide federal grants, ready-to-use templates, and technical support to help underfunded institutions develop the necessary systems for tracking occupational health and biosafety requirements.

485. Syneos Health

I am responding: On behalf of an organization

Name:

Name of Organization: Syneos Health

Type of Organization: Other

Type of Organization - Other: Clinical Research Organization

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Syneos Health is a leading fully integrated biopharmaceutical solutions organization built to accelerate customer success. We translate unique clinical, medical affairs and commercial insights into outcomes to address modern market realities. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. As a clinical research organization, Syneos Health supports sponsors across clinical development by helping design and operationalize studies, select and activate research sites, coordinate with investigators and institutional review functions, manage investigational products and study procedures, monitor trial conduct, and support safety and regulatory reporting. These activities frequently involve multicenter and global studies conducted across academic, hospital, community, and independent research settings, including trials of biologics, genetically modified products, live biotherapeutics, and other modalities that may fall within the draft policy. We are commenting because the policy's definitions, applicability criteria, review pathways, reporting obligations, and implementation requirements will directly affect site feasibility and activation, institutional coordination, study timelines, patient enrollment and access, and the consistent conduct of clinical research. Our perspective is intended to help NIH establish a scientifically grounded, risk-proportionate, and operationally workable framework that protects participants, clinical personnel, communities, and the environment without imposing unnecessary barriers to research.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Product-scope definitions should be sufficiently precise to avoid confusion and inconsistent interpretation of review and implementation requirements.

NIH should define the evidence needed to establish that a product is capable of shedding, replicating, or integrating. Applicability determinations should be grounded in scientifically justified biological hazards and credible exposure pathways rather than therapeutic modality alone, so that oversight remains proportionate to the actual risks of the investigational product and associated research activities. In particular, detection of noninfectious product material should be distinguished from a credible exposure or transmission hazard. The term "higher risk manipulations" should reflect the biological hazard, exposure pathway, and available controls.

Clinical examples should clearly identify the product modalities covered by the policy, including purified recombinant proteins and monoclonal antibodies, transiently modified cells, nonintegrating nucleic acid products, live biotherapeutics (including live vaccines), and approved products used in research. NIH should clarify that manufacture using genetically modified cells, including commonly used production cell lines such as CHO cells, does not, by itself, bring clinical administration of a purified protein or monoclonal antibody within scope. Similarly, potential therapeutic adverse effects should not automatically classify a protein as a toxin for biosafety oversight.

NIH should also clarify institutional applicability across affiliated hospitals, independent investigator practices, research networks, and non-U.S. sites receiving NIH funding, including sites in Canada. A standardized applicability checklist and a searchable, regularly updated mechanism for verifying which institutions are subject to the policy by virtue of NIH funding would reduce repeated interpretation, support consistent decisions across sites participating in the same trial, and allow sponsors and CROs to plan startup timelines accurately.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Syneos Health supports oversight proportionate to the product, procedures, and credible biosafety risks. The framework should make clinical trial conduct easier rather than more cumbersome so that sites can start efficiently, patients can enroll promptly, and studies can be completed without avoidable delay. NIH should establish distinct tiers of review and submission requirements based on product-risk categories. Well-characterized products with negligible transmission or exposure risk should be eligible for delegated review under defined criteria, with escalation to the full IBC when material risk is identified.

NIH should expressly permit a qualified central IBC to perform a shared product and protocol assessment for multicenter trials. Participating institutions should retain responsibility for local facilities, personnel, handling procedures, waste management, and emergency response. A common sponsor-provided biosafety dossier, supplemented by a concise site-specific assessment, would reduce duplication while preserving local accountability. We also suggest to have a standardize IBC questionnaire as well for the study application.

Where NIH has established an applicable containment determination, other institutions should be able to reference that determination, subject to confirmation that the product and conditions are comparable. Repeated assessment of the same scientific question should be minimized.

The final policy should distinguish amendments affecting the biosafety assessment from administrative, protocol-management, product-management, or clinical changes without biosafety implications. Sites should be able to document through a proportionate process that a change does not require further IBC review.

NIH should clearly reconcile the respective responsibilities and scope of FDA and NIH review and explain how the provision concerning oversight by another federal agency interacts with institutional IBC requirements.

Parallel review across IBC, IRB, pharmacy, infection prevention, occupational health, FDA, and local

authorities should be supported and expected where feasible, rather than allowing dependent or sequential review steps to create avoidable startup delays.

We welcome the provision allowing IBC oversight to conclude after the final dose, subject to the biosafety assessment. NIH should establish consistent closure criteria addressing remaining shedding precautions, specimen handling, and other exposure risks. The policy should explicitly recognize that biosafety risk may change substantially across the clinical trial lifecycle: risks associated with investigational product preparation and administration may differ from those during clinical monitoring or long-term follow-up. Oversight requirements should reflect the activities and credible exposure risks remaining at each stage, and long-term clinical follow-up alone should not require continued IBC oversight once relevant biosafety activities and risks have ended.

For studies requiring continued oversight, NIH should permit a focused, low-effort renewal process comparable to proportionate IRB continuing review when the product, procedures, and risk profile remain unchanged, rather than automatically requiring a complete de novo submission every three years. De novo review would add cost and burden and could disrupt trials at different stages of conduct and participant follow-up without a corresponding biosafety benefit.

3. Continued utility of Risk Groups: No comment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): For institutions participating voluntarily, NIH should provide accessible tools, role-specific training, technical assistance, standardized procedures, and external IBC options. Implementation should not inadvertently restrict research to large academic centers. Clear pathways and practical access to external expertise would help qualified smaller and community research sites offer clinical research as a care option, particularly where patients are geographically dispersed or have limited access to specialized academic centers, while avoiding slower enrollment and disproportionate administrative burden.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: For public disclosure, NIH should permit a standardized safety summary identifying the event, relevant risk, response, and corrective actions. Clear guidance and data-protection mechanisms should protect personal, proprietary, confidential product, and security-sensitive information so that disclosure requirements do not dissuade sponsors from conducting clinical trials in the United States. Lower-risk, locally managed incidents without material public-health implications should not routinely require individual public reports where aggregate reporting would provide comparable public benefit.

For rapid incident reporting, NIH should define the responsible institutional official, start the 24-hour notification clock when that official has sufficient information to determine that the event may meet reporting criteria, specify the minimum information required initially, and clarify expectations when reportability is uncertain. Institutions should take immediate protective action while determining reportability, and a brief preliminary notification should be acceptable while an investigation continues. NIH should distinguish urgent biosafety events from administrative deficiencies without an immediate safety consequence and establish proportionate response expectations.

NIH should clarify the relationship between biosafety incident reporting, clinical safety reporting, and

protocol deviation management. For issues affecting multiple sites, coordinated reporting with site-specific supplements should be permitted to avoid duplicative reports while preserving each institution's responsibility for its local response. Public documentation and rapid reporting may require new contractual and operational interfaces among sponsors, CROs, sites, and external IBCs; NIH should be aware that these requirements will have resulting costs and implementation burden that impacts sites, sponsors, and even NIH resource demand.

Transparency requirements should permit standardized public summaries while protecting proprietary, personal, and security-sensitive information. Minor incidents without material public-health implications should not require individual public posting. Requirements should not inadvertently discourage reporting, deter sponsors from conducting U.S. trials, create inconsistent institutional implementation, or add burdens that delay site activation and patient enrollment without improving safety.

The meeting-minutes template should permit concise documentation of delegated, expedited, reliance-based, renewal, and closure determinations. It should capture the rationale for the biosafety decision and any site-specific conditions without requiring repetition of product-level information already contained in a reusable biosafety dossier.

NIH should provide completed examples for common clinical scenarios and training on consistent use of both templates, including examples applicable to smaller and community sites. Template instructions should also identify appropriate protections for proprietary, personal, and security-sensitive information and support standardized public summaries rather than disclosure of confidential product details.

6. Other feedback relevant to this resource: Syneos Health recommends a transition period longer than 12 months following publication of the final policy and all essential implementation materials, with phased implementation where appropriate. Existing approvals and ongoing trials should be grandfathered until scheduled review unless a material biosafety concern warrants earlier reassessment. A longer transition is needed to prevent a review bottleneck and allow sites and IBCs sufficient time to augment staffing, establish processes, and complete training. Administrative transition should not unnecessarily interrupt participant dosing, enrollment, or follow-up.
NIH should anticipate for how federal and institutional reviewer bandwidth will be increased to accommodate the additional workload created by the policy's expanded scope.

Priority implementation resources should include clear rollout communications and standardized training designed to prevent misinterpretation and inconsistent implementation across institutions, for example:
• A clinical applicability decision tree and product-specific examples.
• Standard submission requirements and a reusable product-level biosafety dossier.
• Criteria for delegated review, amendment assessment, renewal, and closure.
• Model reliance agreements and responsibilities for central IBC arrangements.
• Incident-reporting decision tools and public-disclosure guidance.
• Training tailored to investigators, research coordinators, pharmacy personnel, and community sites.

NIH should evaluate how from the broader R&D and clinical trial planning perspectives, this policy evaluation should consider how these IBC policies, will in part influence the country/site selection and

patient access aspects of trial conduct. Notably, the assessment should specifically monitor whether the policy concentrates research in large academic centers or unintentionally encourages sponsors to move early-phase trials outside the United States. A scientifically proportionate and consistently implemented framework would help preserve U.S. participation in innovative clinical trials while ensuring that expanded oversight delivers meaningful biosafety benefits.

486. University of Louisiana at Lafayette

I am responding: On behalf of an organization

Name: Robin Schneider-Broussard

Name of Organization: University of Louisiana at Lafayette

Type of Organization: Academic Institution

Role: Other

Role - Other: Director of Research Integrity

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Vaccine research, basic science understanding gene function

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see our attached letter.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see our attached letter. There are significant concerns about overlaps of oversight causing confusion, multiple reporting lines and duplicative reporting and enforcement actions.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The potential removal of funding from institutions and requiring posting of minutes and incidents is more likely to discourage people from pursuing NIH funding than from encouraging voluntary compliance from non-NIH funded institutions. Please see the attached letter for more discussion.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Please see our comment letter.

Description: Comment letter from UL Lafayette

487. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Other

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious diseases and cell & gene therapy

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: While the intent and objectives of the proposed policy are appreciated, the policy would benefit from greater clarity and precision in its definitions, scope, and application. Several provisions appear open to interpretation, which may lead to inconsistent implementation across institutions and create uncertainty regarding oversight responsibilities. It is recommended that the policy provide more explicit definitions of biohazards for the purposes of oversight, clarify the criteria for determining which activities fall within its scope, and address any potential gaps or ambiguities in oversight. These refinements would promote consistent interpretation and implementation, minimize the risk of misinterpretation, and ensure that the policy achieves its intended objectives effectively.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The proposed tiered oversight approach should be carefully calibrated to risk while ensuring clear lines of authority, accountability, and responsibility for administering institutional biosafety programs. The additional administrative and oversight requirements outlined in the policy may place a disproportionate burden on smaller universities and research institutions, particularly those without a dedicated Environmental Health and Safety (EHS) office or a Biosafety Officer (BSO). These requirements may also discourage participation by Institutional Biosafety Committee (IBC) members due to the increased workload and administrative responsibilities. Maintaining databases and fulfilling additional reporting and documentation requirements could further strain institutions with limited resources.

The Biosafety Officer is a cornerstone of an effective institutional biosafety program. Therefore, appointing a qualified BSO should be a mandatory requirement for all NIH-funded institutions conducting research involving biohazards, rather than a requirement limited to institutions operating BSL-3 facilities. Since a substantial proportion of life sciences research involving biohazards is conducted at BSL-2, limiting the requirement to institutions with BSL-3 programs leaves a significant gap in biosafety oversight.

Furthermore, assigning responsibility to the BSO without providing commensurate authority, institutional support, adequate resources, and a clear reporting structure may undermine the

effectiveness of the biosafety program. The policy should explicitly define the BSO's authority, responsibilities, and relationship with institutional leadership, the IBC, and other relevant offices. It should also clarify who within the institution is responsible for reporting biosafety incidents and ensuring regulatory compliance, recognizing that the BSO's operational role may not include the authority to report directly on behalf of the institution.

Finally, institutions should be required to demonstrate that they have an adequately resourced and effectively supported biosafety program, including qualified personnel with clearly defined authority and responsibilities, before an NIH award is issued. The policy should also incorporate a risk-proportionate implementation framework that accounts for institutional size, research activities, and available resources while maintaining appropriate standards of biosafety oversight. These measures would strengthen accountability, address gaps in oversight, and support consistent implementation without imposing disproportionate administrative burdens on smaller institutions.

3. Continued utility of Risk Groups: Risk Groups (RGs) can serve as a useful starting point for risk assessment; however, they should be considered a baseline rather than a definitive determinant of the required level of biocontainment. The appropriate containment level should be established through a comprehensive, evidence-based risk assessment that considers the characteristics of the biological agent, the nature and purpose of any genetic modifications, the experimental procedures, potential exposure routes, and the best available scientific information. The expertise and judgment of the Institutional Biosafety Committee (IBC) should play a central role in this process.

However, many IBCs, particularly at smaller institutions, may lack the specialized expertise and experience needed to assess complex or emerging biological risks independently. Therefore, NIH and FDA should provide clear guidance, technical assistance, training, and sustained outreach to help institutions apply the policy consistently and appropriately. This support is especially important when assessing genetically modified agents for which existing Risk Group classifications may not adequately reflect the risks associated with the proposed research.

Furthermore, communication regarding the policy should be led directly by relevant federal staff and policy makers, rather than relying primarily on contractors. Institutions need opportunities to hear the policy's rationale, interpretation, and implementation expectations directly from the federal officials responsible for developing and administering it. Direct engagement would improve transparency, facilitate meaningful dialogue, and enable institutions to obtain authoritative clarification on complex or ambiguous provisions.

Finally, the Biosafety in Microbiological and Biomedical Laboratories (BMBL) should be reviewed and updated regularly to reflect advances in life sciences research, emerging technologies, and evolving understanding of biological risks. Keeping the BMBL current, alongside accessible federal guidance and technical support, would help ensure that risk assessments and containment decisions remain scientifically sound, proportionate to the actual risks, and consistently applied across institutions.

There is also concern that reporting potential issues involving gain-of-function research, particularly those that may pose significant biological risks, could create reputational concerns for institutions and add substantial administrative burdens. Without clear, consistent, and well-defined reporting

procedures, institutions may face uncertainty regarding what must be reported, when reporting is required, and how such information will be handled. The policy should establish a clear, streamlined, and transparent process for identifying, evaluating, and reporting potential concerns, with well-defined reporting thresholds, responsibilities, and timelines. It should also ensure appropriate confidentiality and consistent handling of reported information to minimize unnecessary reputational concerns while maintaining accountability and public trust. A proportionate, straightforward process would help institutions address potential risks promptly and responsibly without creating unnecessary administrative complexity or discouraging the reporting of legitimate biosafety concerns.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): A major concern regarding voluntary compliance is the lack of clarity about the applicability of the policy to research supported indirectly through NIH funding. For example, if an academic institution subcontracts or collaborates with a contract research organization (CRO) using a portion of an NIH-funded award, it is unclear whether and under what circumstances the policy would apply to the CRO, particularly when the CRO does not receive funding directly from NIH. Such ambiguities have persisted in the interpretation and implementation of the NIH Guidelines, highlighting the need for explicit, practical, and authoritative guidance. Institutions and research partners need clear definitions of the entities, activities, and funding arrangements covered by the policy, along with transparent mechanisms for resolving questions about applicability. These requirements should be clearly articulated in the policy itself rather than left to interpretation, as the absence of explicit provisions may result in inconsistent implementation and significant gaps in oversight.

Another important concern is the application of the policy to small biotechnology companies and other research organizations that may lack formal biosafety oversight structures or adequate institutional resources. Voluntary compliance alone may not be sufficient to ensure consistent and responsible oversight across these entities. The policy should therefore establish clear expectations and provide practical guidance, technical assistance, and scalable oversight mechanisms that accommodate organizations of different sizes and capacities without compromising biosafety standards.

Ultimately, for the policy to achieve its intended objectives, its scope and implementation should extend beyond research directly funded by NIH, where appropriate, through coordinated adoption and harmonization across other relevant federal agencies, including the FDA and Department of Defense (DOD). A consistent, government-wide approach would help address gaps arising from differences in funding mechanisms, subcontracting arrangements, and agency-specific requirements. Without clear applicability criteria, effective interagency coordination, and enforceable oversight expectations, the policy risks creating a fragmented system in which similar research activities are subject to different standards depending on the funding source or institutional affiliation.

Similar to the ClinicalTrials.gov registration and reporting framework, which applies to certain clinical trials regardless of whether they are NIH-funded, a comparable mandatory reporting and registration mechanism should be established for relevant biotechnology research involving potential biological risks. Such a requirement should apply to biotechnology companies, contract research organizations (CROs), and contract development and manufacturing organizations (CDMOs), irrespective of their direct funding source. A centralized database would improve transparency, facilitate consistent oversight, and help prevent gaps in biosafety accountability across the research and development landscape. The policy

should clearly define the research activities subject to registration, the information to be reported, the responsible parties, and the reporting timelines. Appropriate safeguards should also be established to protect confidential business information and sensitive research details while ensuring that relevant authorities have access to the information needed for effective oversight. A mandatory, streamlined, and consistently enforced reporting framework would strengthen biosafety governance beyond the scope of federally funded research alone.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The Draft Incident Reporting and Draft Meeting Minutes Templates require greater clarity and more detailed instructions to ensure consistent implementation across institutions. For incident reporting, the policy must explicitly define what constitutes a reportable incident, who is responsible for submitting the report, to whom it must be submitted, and the applicable reporting timelines. A strict 24-hour reporting deadline may impose a substantial administrative burden, particularly on smaller institutions with limited biosafety personnel and resources. Incident assessment often requires preliminary fact-finding, consultation with research personnel, review by the Institutional Biosafety Committee (IBC), and coordination with institutional officials. These activities may not be feasible within 24 hours.

The policy should therefore clearly distinguish between an initial notification and a comprehensive incident report. For example, an initial notification could be required within 24 hours of identifying a qualifying incident, with a more detailed report submitted within a clearly defined subsequent period after an appropriate investigation has been conducted. The policy should specify the minimum information required in the initial notification, the additional details expected in the full report, and the circumstances under which updates or extensions may be appropriate. A proportionate reporting framework should also account for institutional capacity while ensuring that significant biosafety concerns are communicated promptly and addressed effectively.

Another important concern is the potential public disclosure of information contained in incident reports. If institutions perceive that preliminary or incomplete reports could be publicly released without adequate context, they may be less forthcoming in reporting incidents, potentially undermining the primary objective of the policy. The policy should clearly explain how incident reports will be handled, who will have access to them, and under what circumstances information may be disclosed publicly. It should also establish transparent procedures for protecting confidential, sensitive, and preliminary investigative information, consistent with applicable disclosure requirements. These safeguards should encourage timely, accurate, and complete reporting rather than inadvertently discourage it.

Similarly, the Draft Meeting Minutes Template should include explicit instructions regarding the information that must be documented and the information that may be redacted before submission or public release. The policy should specify the applicable criteria for redaction and provide numerous practical examples addressing confidential business information, proprietary research details, sensitive biological information, personnel information, and preliminary discussions that could be misinterpreted without appropriate context. It should also clarify the distinction between information that must be retained in official institutional records and information that may be redacted from versions submitted to federal agencies or made publicly available.

Overall, both templates should be accompanied by detailed instructions, illustrative examples, and

standardized procedures to minimize ambiguity and administrative burden. These requirements should be practical for institutions of varying sizes and resources while preserving transparency, accountability, and the timely reporting of significant biosafety concerns.

6. Other feedback relevant to this resource: Many institutions may not be adequately prepared to implement the proposed policy within the anticipated timeframe, particularly given the need for greater clarity in several of its provisions. Institutions will require sufficient time to interpret the requirements, assess existing biosafety infrastructure, identify resource gaps, establish appropriate reporting mechanisms, and develop internal procedures. NIH should consider extending the implementation timeline and providing a phased approach that allows institutions to prepare adequately before compliance becomes mandatory.

Effective implementation also requires direct communication with institutional leadership and administrative offices that have the authority to allocate resources and establish institutional priorities. Currently, information about the draft policy often flows through multiple administrative levels, from the Biosafety Officer (BSO) to the Head of Environmental Health and Safety (EHS), and subsequently to the Office of the Vice President for Research (VPR). This communication pathway may delay awareness and leave biosafety personnel responsible for implementing requirements without the institutional authority or resources necessary to do so effectively. NIH should therefore communicate policy requirements, implementation timelines, and institutional expectations directly to the VPR, Office of Sponsored Programs, and other relevant institutional leaders, while ensuring that BSOs and biosafety program personnel remain closely involved in implementation planning.

NIH should also consider providing dedicated financial and technical resources to support the development, strengthening, and implementation of institutional biosafety programs. Additional requirements for reporting, documentation, database maintenance, committee coordination, and incident investigation will increase the workload of existing biosafety personnel. Without additional staffing and institutional support, these responsibilities risk contributing to staff burnout and weakening the effectiveness of existing biosafety programs. Implementation resources should be proportionate to institutional size, research activities, and available infrastructure, with consideration given to smaller universities and institutions with limited administrative capacity.

Another area requiring additional guidance is coordination among Institutional Biosafety Committees (IBCs), Institutional Animal Care and Use Committees (IACUCs), and Institutional Review Boards (IRBs). There appears to be considerable uncertainty and resistance regarding the extent of coordination required among these committees. In many institutions, IRBs do not routinely engage with IBCs, potentially creating gaps in the review of research protocols involving biological agents, genetically modified materials, or other biosafety considerations. These coordination challenges may be particularly pronounced at smaller universities and across the biotechnology industry, where dedicated compliance personnel and established mechanisms for inter-committee communication may be limited.

NIH should provide explicit guidance on when and how these committees are expected to communicate, share relevant information, and coordinate their reviews, while respecting their distinct regulatory responsibilities. Practical implementation resources, including sample institutional procedures, workflow diagrams, role definitions, training materials, and case-based examples, would help institutions establish

effective coordination mechanisms.

Overall, successful implementation will require more than issuing policy requirements. NIH should provide clear guidance, direct engagement with institutional leadership, adequate implementation time, targeted financial and technical support, and practical tools for integrating biosafety oversight into existing institutional research governance structures. These measures are essential to ensure consistent implementation, avoid disproportionate burdens on smaller institutions, and maintain sustainable and effective biosafety programs.

488. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of the policy should focus on biological agents defined as „bacteria, viruses, fungi, or parasites that cause human disease „. Oversight over genetically modified agents and organisms should be separate. Lower risk materials should remain with local oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered review would be helpful by the way the policy is written is rather confusing. Information in multiple sections though overlaps and is contradicting. There should also be exemptions or admin registrations for low level risk material.

3. Continued utility of Risk Groups: Risk groups are useful for hazard communication and material characterization. But risk group along cannot dictate containment levels. Many elements must be taken into account including volume, procedure, expertise, facility access and more.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: A one size fits all template will not work for all institutions. Additionally, many of the terms mentioned in the incident section are vague and impossible to follow. The timing of reporting should also reflect the risk level. 24h time period should not apply to low risk
Incidents

6. Other feedback relevant to this resource: Federal funding will need to accompany this mandate to ensure correct and efficient application of the policy. Fund will be required to update registration systems, oversight programs, training, especially for smaller and low resource institutions

489. Brian Eggert

I am responding: On behalf of myself

Name: Brian Eggert

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Included in attached PDF.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Included in attached PDF.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: For IBC minutes, consider providing more flexibility for institutions to develop their own templates provided that all of the required elements are included.

6. Other feedback relevant to this resource: Included in attached PDF.

490. Kara De Leon

I am responding: On behalf of myself

Name: Kara De Leon

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The scope of the new policy states that it covers all biomedical research; however, the policy is broader than this. The term biomedical may not apply to all types of research that could fall under this list of biohazards, yet as an institution receiving NIH funds, all PIs with research that includes any one of the listed biohazards would fall under the policy regardless of whether their focus is biomedical.

The definition of biohazards is missing some important biohazards that have the potential to be hazardous to human health. The biohazard risk is focused on humans but animal and plant pathogens also have inherent risks to humans either directly or due to the risk they have on the environment that can then impact human health. Having one unified guidance for these risks makes more sense than each institution developing their own policies, which could differ significantly.

Biohazard Number 4 should include not just cells or organisms, but samples that may contain 1,2, or 3 above. Currently, it is not clear how one would evaluate tissue samples or blood samples that could contain contaminating pathogens, or environmental samples likely to contain viruses or pathogens.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The requirement of an NIH petition for determination of minimum biocontainment level for emerging, novel, or zoonotic biological agents for which the RG classification of containment level is not available in the BMBL should be limited to specific circumstances where there is great uncertainty after a standard risk assessment. Many organisms routinely treated as RG1 organisms are highly unlikely to cause disease and this is clear from the risk assessment. Yet, they do not have an official RG classification and/or are not listed in BMBL. This will likely pose a major bottleneck and unnecessary assessment by the NIH. If this requirement for an official determination is kept, the determinations should be housed online in a form that can be updated continuously to remove redundancies in assessments.

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Section IV-2, second bullet – Which risk groups should be clarified. None are listed, but Section IV-3, second bullet lists RG1 so presumably Section IV-2 is referring to RG2 and greater.

Once the policy is implemented, it should include details on how to handle research with current IBC approval. Will these be grandfathered in for the remainder of their approval period (up to 3 years remaining) or will they need to be reassessed within the updated policy? Will minor changes to the project require full reassessment with the updated policy or could these also be grandfathered in?

491. BOLB Inc.

I am responding: On behalf of an organization

Name: Ling Zhou

Name of Organization: BOLB Inc.

Type of Organization: Commercial Entity (Biotech/Device/Pharmaceutical Company/Small Business)

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious disease control

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: We welcome NIH's emphasis on layered mitigation. As a developer of UV-C disinfection technology, and seeing how efficacious it can be, we offer three recommendations for the final policy:
1. Recognize UV-C as an engineering control. List room-air and room-surface UV-C disinfection among the examples of facility-based mitigation, alongside ventilation, decontamination systems and biosafety cabinets, especially for aerosol-generating BSL-2 work and BSL-3 suites.
2. Evaluate on performance, not technology type. Give IBCs and biosafety officers guidance on criteria such as:
equivalent clean airflow (as in ASHRAE Standard 241);
-independent efficacy testing;
-recognized safety certification;
-interlocks for whole-room use;
-occupant exposure within ACGIH limits when PPE is not worn.
3. Record the exposure route. Ask that incident reports record the likely route of exposure, to build a national evidence base on aerosol-related lab-acquired infections.

Why this matters
1. Aerosols outside the cabinet are the gap. Lab-acquired infections may come from aerosol exposures that go unnoticed. Pathogen aerosols can be generated outside the biosafety cabinet, during

centrifugation, pipetting, spills and opening vessels. At BSL-2, open-bench aerosols are protected only by general ventilation.
2. During work, UV-C stays in the upper room. Upper-room UV-C has long been used in healthcare against airborne tuberculosis (NIOSH guidelines). It inactivates airborne organisms continuously while staff are present. It adds equivalent air changes well beyond ventilation alone, at a fraction of the energy cost.
3. Between sessions, UV-C can flood the empty room. After a spill, at day's end or before maintenance, it decontaminates exposed surfaces and air within minutes. It leaves no chemical residue and needs no aeration downtime. Interlocks, door switches and occupancy sensing ensure no one is exposed.
4. In BSL-3 and BSL-4 suites, full PPE widens the options. Where staff wear PPE that covers skin and eyes, as in BSL-4 suit labs, the risk of UV-C exposure is much lower. This allows broader in-room use during work, once it is verified that the PPE blocks UV-C.
5. The technology is ready. Modern UV-C LED systems are instant-on, mercury-free and occupancy-sensed, and can be certified for occupied spaces (UL 8802).

492. James Pharr

I am responding: On behalf of myself

Name: James Pharr

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Other

Role - Other: Safety

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Overall I agree with the expansion of the policy to include biohazards, but I feel the implementation is lacking from the holistic, risk-based approach to biosafety that was discussed in the initial listening sessions.
1) Plants are not included, leading to a major gap in oversight. While I appreciate the NIH's focus on human health and wellbeing, the departure from the current NIH guidelines which include plant work appears to assume there are no conceivable instances where deleterious modifications to plants/plant pathogens could lead to public safety concerns (e.g., GDMO agricultural crops that select for disease susceptibility, or increased tropism of exotic plant pathogens to agriculturally important crops, etc.). This will ultimately just add to the patchwork of regulations rather than synthesize a cohesive system of biosafety oversight.
2) The second definition of genetic modification is problematic; the clause covering stable genome alterations by passaging, reassortment, or chemical or radiological means would pull a lot of ordinary material into registration. I suggest deleting it or narrowing it to intentional modification meant to produce a harmful effect.
3) The definition of toxin is limited to proteins and peptides. That misses non-protein biological toxins such as lipopolysaccharide (LPS, aka endotoxin) and alkaloid-based toxins like those from poison dart frogs. It also doesn’t clearly distinguish a full holotoxin from a harmless subunit. I would also suggest having a threshold for requiring registration. We currently only require registration of toxins of biological origin with an LD50 <1mg/kg bodyweight demonstrated in a mammalian species - this avoids policy mismatch between registering and reviewing all biological toxins and not reviewing chemical toxins (e.g., nicotine with an LD50 ~3 mg/kg bodyweight).
4) Work currently listed as exempt under III-F of the Guidelines, would no longer be exempt. This would increase administrative burden on research and safety staff.
5) “Low risk transgenes” should be more clearly defined (e.g., not containing oncogenes, clinically relevant antibiotic resistance genes, toxin-encoding genes, etc.)
6) Section IV-2 makes IBC approval a precondition for all in-scope work, including new BSL-2 agents and human source material (HSM) work, which would block a single blood draw or cheek swab until the

protocol has had full committee review, drastically slowing down current process. I would recommend amending language to allow for DMR unless material is either known or suspected to contain adventitious agents, rather than the ambiguous "may contain" language.
7) Public posting of incident reports is likely to adversely affect safety. It is hard enough to get people to report incidents in the lab due to perceived burden of post-incident follow-up. We conducted an informal survey with our researchers and they indicated that they would be much less likely to report if they knew it would be publicly posted for many reasons: PIs pressuring staff (either unintentionally or overtly) not to report; embarrassment, fears that the reports would be weaponized against individual PIs and/or the entire institution given the current political climate. It would also further erode public trust in research institutions by construing them as potentially unsafe or reckless in public opinion. If construction companies were required to report every injury requiring first aid, they would also likely be construed as unsafe. In addition, public transparency must be balanced against the goals and requirements of privacy laws (e.g., HIPAA, state privacy laws, collective bargaining agreements) and other policy concerns (e.g., protection of trade secrets, promoting a just and fair culture of incident reporting). With respect to incident reports, which often contain sensitive personal information, NIH should permit anonymized, aggregated reporting with identifiable information disclosed to appropriate governmental officials only when there is a legitimate need to know (e.g., public health investigation).
8) De novo registration will likely result in some materials being inadvertently omitted, leading to an NIH reportable event. Our current process involves a 3-year renewal in which research staff must attest that research is ongoing and to certify whether each of the registered materials are still in active use, are in cold storage, or have been terminally inactivated and properly disposed of/removed from the lab. Something like this is a better approach than starting from scratch every 3 years.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): NIH expects Funded Institutions to perform these responsibilities for ALL non-NIH funded research within the policy's scope. Yet, the policy contains no mechanism to ensure that institutions are fully reimbursed for costs associated with providing these services. Requiring blanket immediate NIH notification is an additional step/administrative burden and is not risk-based. While it may be justified for some instances (e.g., potential release into community), it is not justified for others (e.g., protocol renewal is submitted 1 day late or the IBC meeting has to be pushed back due to scheduling, causing a protocol to exceed the 3 year approval maximum). NIH should also empower the IBC to provide a re-review/reregistration grace period of up to 90 days to accommodate circumstances in which the IBC cannot complete its review within the specified period (delays due to scheduling conflicts, returned submissions for additional comments, PIs on sabbatical, etc.)

3. Continued utility of Risk Groups: RGs are a starting point of risk assessment. If RG is equated to containment, then there is no mechanism in which containment should be lowered. Keep an established list of both.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): congressional action to create a comprehensive biosafety policy that synthesizes all the disparate areas currently overseen in a patchwork fashion by various agencies, regardless of funding source. NIH is attempting something beyond its true scope, and while admirable, will likely fall short of what is truly needed.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The template for the minutes is embedded into the software platform we use; changing this would be cost-prohibitive, and manually entering into a word document would be a tremendous increase in administrative burden. Incident reporting low risk incidents and injuries is not a risk-based approach and will subvert local safety efforts.

6. Other feedback relevant to this resource: Implementation timeline is much to quick for such sweeping changes. 50 years of established biosafety practices and policy and integrated institutional components can't be repealed and replaced within just 6 months. It would place an undue burden on staff responsible for implementation, especially with no guarantee of additional funding or support and substantial expansion of duties and review.

493. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Research Participant/Patient Advocacy Organization/Patient Advocate/Caregiver

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Infectious Disease Research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comments-for-NIH-Draft.docx

Description: Comments for NIH Draft

The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I

The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.

Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.

Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment, and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.

Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.

Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.

Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.

Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.

Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.

Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting

relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.
Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C

The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.

Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance, engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule

when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.

Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.

Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.

If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee.

Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.

Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual

institutional biosafety duties for excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

494. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Policy Does Not Clearly Reduce Burden for Low-Risk Research

Observation
A stated goal of modernization is reducing unnecessary burden for low-risk activities.

Real-World Implementation Impact
Many activities currently viewed as low risk may still require protocol submission, delegated review, documentation, committee reporting, and public records management.
Investigators may not perceive a meaningful reduction in burden.
Why This Matters
Regulatory credibility is strengthened when oversight requirements are clearly aligned with risk.

Recommendation
NIH should identify additional exemptions, registrations, or administrative review pathways for activities with well-established risk profiles.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

495. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: RG1 Materials May Be Subject to Substantial New Oversight

Observation
The policy excludes many wild-type RG1 agents but brings numerous low-risk derivatives and commonly used research materials into scope.

Real-World Implementation Impact
Routine plasmids, transgenic models, viral vectors, and other commonplace tools may become subject to new review and documentation requirements.

Why This Matters
Investigators may experience increased oversight despite minimal changes in actual biosafety risk.

Recommendation
NIH should reassess whether certain routinely used low-risk materials warrant formal oversight.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

496. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Clarify Oversight of Well-Characterized Cell Lines
Observation
Well-characterized cell lines receive delegated review despite uncertain linkage to the policy's underlying scope.
Real-World Implementation Impact
Biosafety professionals may struggle to determine which cell lines require review and which are exempt.
Why This Matters
Cell culture research represents a major portion of biomedical research.
Recommendation
NIH should clearly distinguish exempt cell culture, delegated review, and full-review categories.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

497. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Clarify Oversight of Well-Characterized Cell Lines
Observation
Well-characterized cell lines receive delegated review despite uncertain linkage to the policy's underlying scope.
Real-World Implementation Impact
Biosafety professionals may struggle to determine which cell lines require review and which are exempt.
Why This Matters
Cell culture research represents a major portion of biomedical research.
Recommendation
NIH should clearly distinguish exempt cell culture, delegated review, and full-review categories.

498. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Facility Responsibilities Should Reflect Actual Operational Control
Observation
The draft places significant responsibility on PIs for facilities and containment systems.
Real-World Implementation Impact
Investigators generally do not control ventilation systems, certification contracts, building infrastructure, or emergency power systems.
PIs may become responsible for functions outside their authority.
Why This Matters
Safety responsibilities are most effective when aligned with operational control.
Recommendation
NIH should distinguish responsibilities among institutions, facilities personnel, biosafety staff, and investigators.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

499. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Occupational Health Responsibilities Need Clear Triggers
Observation
The policy references occupational health obligations but does not clearly identify when an OHSP is required.
Real-World Implementation Impact
Biosafety professionals may reach different conclusions regarding when occupational health enrollment is necessary.
Why This Matters
Occupational health programs function best when requirements are predictable and consistently applied.
Recommendation
NIH should establish objective triggers and responsibilities for OHSP implementation.

500. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Animal Hazard Oversight Appears Inconsistent
Observation
Several sections address animal-related risks while other provisions appear to exclude certain animal-only pathogens.
Real-World Implementation Impact
Institutions may struggle to determine which animal studies fall within scope.
Why This Matters
Animal biosafety programs depend upon clear oversight boundaries.
Recommendation
NIH should clarify how animal-specific pathogens fit within the framework.

501. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Plant Exclusions and Environmental Oversight Are Not Fully Aligned
Observation
Plants appear largely excluded while environmental considerations remain prominent throughout the draft.
Real-World Implementation Impact
Biosafety professionals may be uncertain when environmental review obligations apply.
Why This Matters
Environmental considerations should align with scope definitions.
Recommendation
NIH should explicitly explain the relationship between plant exclusions and environmental risk assessment.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

502. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Biological Agent Definitions Require Revision
Observation
The definition of biological agent appears narrower than how the term is used throughout the policy.
Real-World Implementation Impact
Biosafety professionals may encounter situations where covered activities do not clearly fit within the definition.
Why This Matters
Definitions are foundational to consistent implementation.
Recommendation
NIH should harmonize definitions with policy usage.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

503. University of California San Diego

I am responding: On behalf of an organization

Name: Corinne Peek-Asa

Name of Organization: University of California San Diego

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): UC San Diego conducts cutting-edge biomedical, clinical, environmental and engineering research across the School of Medicine, Skaggs School of Pharmacy and Pharmaceutical Sciences, Scripps Institution of Oceanography, Jacobs School of Engineering, and affiliated health centers.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The Policy, as drafted, states: "The NIH Biosafety Policy covers all biomedical research, in laboratory settings, involving biohazards."

This language is ambiguous regarding how it applies to synthetic biology, computational/in silico design, plants, arthropods, animal pathogens, toxins, and non-infectious materials.

UC San Diego requests examples illustrating scope application to common categories of research. If the intent is to cover all biomedical research involving biological agents, the Policy would substantially expand oversight into historically low-risk activities, increasing administrative burden without a demonstrated biosafety benefit.

We recommend a limiting threshold. One that requires a credible, scientifically plausible risk of causing disease in healthy adult humans under reasonably foreseeable laboratory exposure routes and quantities. We propose the consideration of removing oversight of previously exempt toxins, self-aggregating proteins, genetically modified Risk Group 1 organisms, and other low-risk activities under existing NIH Guidelines.

If non-human health risks are intended to be addressed, we would propose the establishment of a separate, clearly defined threshold for environmental, agricultural, ecological or animal-health consequences rather than incorporating them through open-ended references to "biohazards."

Lastly, the applicability of non-NIH funded research needs to be clarified. As an institution-wide regulation, the Policy imposes compliance obligations on non-NIH work. We propose that the agency limit applicability to NIH-supported research or define clear boundary conditions for affiliates, tenants, leased space, and core facilities.

Numerous terms remain undefined or inconsistently used, including “authorized organizational representative,” “biohazard,” “biohazardous,” “biological toxin protein,” “biosafety officer,” “GDMO,” “primary cells that may be contaminated by adventitious agents,” and “well-characterized cell lines.” Clinical terms such as “shedding,” “replicating,” “integrating,” “higher risk manipulations,” and “product” also require definition.

The term “biological agent” is used inconsistently. The definition referencing bacterial, viral, fungal, or parasitic agents that cause human disease does not encompass “gene drive modified biological agents” or “RG1 wild-type agents.” “Human pathogenic agent” may be more accurate where human disease is specifically intended.

The definition of “toxin” is overly broad and does not describe a toxin. Clarify toxicity characteristics such as LD50/LC50 and whether small molecule toxins are included. The definition of “laboratory research” should be revised to encompass activities that may require biosafety oversight but do not fit BSL/ABSL 1-4, e.g., arthropod containment, clinical research activities, and plants expressing human toxins.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): From the UC San Diego perspective, the strongest answer is to support a tiered oversight framework that preserves institutional risk assessment and calibrates federal involvement to risk. To home in on the federal vs. local suggestion.

Federal role: Set minimum national standards, maintain an authoritative and regularly updated Risk Group classification resource, and publish containment-reduction determinations that can be relied upon across institutions. Provide target NIH review timelines, completeness criteria, and an expedited pathway for urgent public health research. Make determinations and rationales publicly available and searchable.
Local/IBC role: Retain primary authority to conduct research-specific risk assessments and assign or approve containment based on local IBC risk assessment, available engineering and administrative controls, institutional risk acceptance, and internal standards. IBCs should be able to impose more stringent controls when site-specific conditions warrant.
Tiered oversight

Distinguish clearly between activities outside scope, exempt from formal IBC review but subject to institutional documentation, eligible for delegated review, and requiring full IBC review. Provide decision trees and examples.
Expand delegated review for routine low-risk work such as replication-incompetent or non-integrating vectors, reporter-only constructs, cell lines, primary materials, transgenic animals, and low-risk genetically modified organisms, with clear escalation triggers to full IBC review.
Preserve IBC as the primary oversight body with strengthened expertise requirements in biosafety, public health, infectious diseases, and animal research as applicable, and retain the requirement for a Biological Safety Officer for large-scale research.
Risk-proportionate scope

Request a limiting threshold such that covered work must present a credible, scientifically plausible risk of causing disease in healthy adult humans under reasonably foreseeable laboratory exposure routes

and quantities. Reduce scope by removing oversight of toxins, self-aggregating proteins, genetically modified Risk Group 1 organisms, and other low-risk activities previously exempt.
If non-human health risks are addressed, establish a separate, clearly defined threshold for environmental, agricultural, ecological, or animal-health consequences rather than incorporating them via open-ended “biohazard” references.
Implementation

Extend implementation timeline to at least 12 months, provide model templates, risk assessment tools, delegated review templates, incident reporting templates, redaction guidelines, and public meeting minute formats before effective date.
Clarify NIH review process: what constitutes an initial request, whether determinations apply to individual experiments or categories, and scope and applicability of each determination, criteria for renewed review, and documentation for IBCs relying on prior determinations.

3. Continued utility of Risk Groups: The Draft Policy relies heavily on Biosafety in Microbiological and Biomedical Laboratories (BMBL) for agent-specific containment. BMBL does not provide Risk Group classification and lags behind emerging research. Institutions have historically used NIH Guidelines, WHO, Public Health Agency of Canada, and other authorities.

NIH should maintain an authoritative, regularly updated Risk Group classification resource and establish a defined process and frequency for review and updates. Risk Group classification, which describes hazard, should be more strongly distinguised from Containment Level, which describes controls. We agree with the University of California Office of the President that the institutional IBCs should retain authority to assign appropriate biosafety level based on local risk assessment, available controls, and specific research.

There is also a need to clarify the NIH review process and timelines, namely what constitutes an “initial request,” when NIH approval is required, and whether determinations apply to individual experiments or categories of research. Target turnaround times, completeness criteria, and an expedited pathway for urgent public health research need to be established.

Decision trees, a searchable repository of prior determinations, and pre-authorized categories for well-characterized agents, attenuated strains, and replication-defective vectors, should be provided.

The IBC should remain the primary body responsible for research-specific risk assessments and containment determinations. IBC expertise requirements should be strengthened to include biosafety, public health, and infectious diseases, with animal research expertise as applicable.

Activities requiring full IBC review from those eligible for delegated review should be clearly distinguished. Requiring review of all genetically modified cells, viruses, or organisms creates a burden for routine low-risk research, particularly genetically modified arthropods and animals. There is also an inconsistency to resolve between delegated review for transgenic organisms at BSL-1/ABSL-1 and BSL-2 minimum containment for “Gene Drive Modified Organisms.”

We also recommend:

Expanding delegated review criteria for replication-incompetent or non-integrating vectors, reporter-only constructs, cell lines, primary materials, transgenic animals, and low-risk genetically modified organisms, with clear escalation triggers.
Clarifying how exemptions operate, transition expectations, and documentation requirements. Distinguish activities outside scope, exempt from formal IBC review but subject to institutional documentation, and eligible for delegated review.
Providing clarification on the Occupational Health and Safety Plan, including when required, expected elements, and scope of NIH oversight.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): From a UC San Diego perspective, the response should emphasize voluntary adoption of NIH-aligned biosafety standards even for research that falls outside mandatory NIH applicability, and propose concrete mechanisms that encourage uptake without imposing federal mandate.

Core principle UC San Diego supports risk-based, proportionate biosafety oversight and can voluntarily align non-NIH funded research with NIH policy principles to promote consistency, interoperability, and safety culture. Voluntary compliance should be facilitated, not penalized, with clear pathways for institutions to opt-in.

Mechanisms to encourage and accommodate voluntary compliance

Institutional assurance model with opt-in tier Allow institutions to submit a voluntary biosafety assurance covering non-NIH funded work under the same assurance framework. NIH could publish a voluntary assurance template and recognize institutions that elect to apply the Policy institution-wide. UC San Diego could map its existing Institutional Biosafety Committee oversight to that assurance to demonstrate compliance for tenants, core facilities, and affiliates.
Public recognition and streamlined review Provide public listing of institutions that voluntarily adopt the Policy, and grant them reliance benefits such as recognition of delegated review determinations and access to the centralized repository of NIH determinations. This creates reputational incentive without regulatory compulsion.
Model guidance, tools, and templates for non-NIH research Make the guidance documents NIH proposes for mandatory implementation available to all institutions, regardless of funding source: risk assessment templates beyond BMBL, delegated review templates, incident reporting decision trees, redaction guidelines, and standardized IBC training. UC San Diego would benefit from these tools for its non-NIH funded biomedical and synthetic biology work.
Carve-out for affiliates, tenants, leased space, and core facilities Define clear boundary conditions so institutions can voluntarily extend oversight to affiliates and core facilities without triggering duplicative federal enforcement. Allow institutions to document voluntary coverage in their Institutional Assurance and maintain institutional records.
Funding-neutral incentives Encourage funders, journals, and collaborators to recognize voluntary adoption as a marker of robust safety governance. NIH could issue a non-binding statement of best practice endorsing voluntary alignment for non-NIH funded research.
Graduated compliance pathway Accommodate phased voluntary implementation with an extended

timeline beyond the 6-month mandatory window, and allow periodic review intervals based on risk level rather than fixed de novo registration every 3 years.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Comments on the Draft Incident Reporting and Draft Meeting Minutes Templates should focus on risk-proportionate transparency and administrative feasibility. Therefore, we recommend the following in these two areas.

Incident Reporting

Adopt a two-tier framework: NIH-reportable/high-consequence incidents reported to NIH and summarized publicly with standardized redactions; lower-risk incidents, near misses, and anomalies kept institutionally and aggregated in a centralized, de-identified database.
Set clear thresholds distinguishing credible exposure/release pathways from contained anomalies where redundant controls remained effective.
Publish a standardized redaction framework identifying information to withhold: sensitive facility/inventory data, security vulnerabilities, proprietary methods, titles, and personal identifiers.
Allow additional time beyond 24 hours or alternative disclosure for security-sensitive or actively investigated incidents.
Clarify relationships among incident reports, IBC minutes, and Institutional Assurances, including confidentiality/retention when incidents span multiple protocols or grants. Provide a decision tree and target NIH review timelines with completeness criteria.
UC San Diego currently uses EHS Risk Management incident forms for student/visitor and occupational incidents, which can be aligned with biosafety reporting to reduce duplication.

Meeting Minutes

Limit public posting to information necessary for transparency and accountability. Provide flexibility on posting timing based on meeting frequency and administrative capacity.
Permit substantially equivalent formats from institutional electronic systems provided required data elements are captured. Publish a machine-readable list of required fields.
Remove training information from minutes templates; training records are dynamic and may contain PII and are better maintained separately.

6. Other feedback relevant to this resource: There is a need to provide implementation guidance for de novo synthesis of genetic sequences, novel constructs without natural counterparts, and standardized biological parts conferring new properties. It is also mandatory to provide criteria and examples for IBC review, delegated review, or no review.

We also support establishing review triggers and minimum safeguards for AI/LLM-assisted biological design tied to high-consequence properties, narrowly defined to avoid impeding general computational research.

In regard to required guidance documents and resources, we'd like to summarize in order to support consistent implementation. NIH should make the following available before the effective date to ensure clarity, ease burden and streamline compliance:

Comprehensive definitions and examples to assess what falls within the scope of policy
Guidance confirming institutional IBC authority for containment and oversight
Risk group classifications
Templated process to request NIH determination for risk group assessment
Guidance on reliance on posted determinations
Searchable repository of prior determinations
Incident report template and decision tree
Standardized redaction guidance
Machine-readable meeting minutes fields
Risk assessment template beyond BMBL
Guidance on environmental/agricultural/animal/arthropod risks
Decision tree distinguishing scope/exemption/delegated/full review
Delegated review template
Standardized IBC training
Occupational health and safety plan template
AI/LLM and synthetic biology examples and determinations.

Uploaded File: UC-San-Diego-NIH-Response-Biosafety-Policy.docx

Description: Full letter of UC San Diego submission of comments to the Draft NIH Biosafety Policy for Research Involving Biohazards issued August 19, 2026. We applaud several aspects of the Draft Policy, including a simplified review structure and terminology, greater transparency through a public incident database and the addition of delegated review. However, we share the University of California's system-wide concerns articulated by the University of California Office of the President in its thoughtful and detailed response. However, we would like to emphasize a number of priorities for UC San Diego.

Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazard

RE: UC San Diego Comments in Response to NOT-OD-26-112, "Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards"

Dear Sir or Madam:

UC San Diego submits the following comments on the Draft NIH Biosafety Policy for Research Involving Biohazards issued August 19, 2026.

As one of ten University of California campuses, UC San Diego conducts cutting-edge biomedical, clinical and environmental research across the School of Medicine, Skaggs School of Pharmacy and Pharmaceutical Sciences, Scripps Institution of Oceanography, Jacobs School of Engineering, and affiliated health centers.

We receive significant NIH funding and operate Institutional Biosafety Committee oversight consistent with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

We applaud several aspects of the Draft Policy, including a simplified review structure and terminology, greater transparency through a public incident database and the addition of delegated review. However, we share the University of California's system-wide concerns articulated by the University of California Office of the President in its thoughtful and detailed response. We would like to emphasize the following priorities for UC San Diego:

1. Define and narrow policy scope to apply oversight proportionate to risk
The Policy, as drafted, states: "The NIH Biosafety Policy covers all biomedical research, in laboratory settings, involving biohazards."

This language is ambiguous regarding how it applies to synthetic biology, computational/in silico design, plants, arthropods, animal pathogens, toxins, and non-infectious materials.

UC San Diego requests examples illustrating scope application to common categories of research. If the intent is to cover all biomedical research involving biological agents, the Policy would substantially expand oversight into historically low-risk activities, increasing administrative burden without a demonstrated biosafety benefit.

We recommend a limiting threshold. One that requires a credible, scientifically plausible risk of causing disease in healthy adult humans under reasonably foreseeable laboratory exposure routes and quantities. We propose the consideration of removing oversight of previously exempt toxins, self-aggregating proteins, genetically modified Risk Group 1 organisms, and other low-risk activities under existing NIH Guidelines.

If non-human health risks are intended to be addressed, we would propose the establishment of a separate, clearly defined threshold for environmental, agricultural, ecological or animal-health consequences rather than incorporating them through open-ended references to "biohazards."

Lastly, the applicability of non-NIH funded research needs to be clarified. As an institution-wide regulation, the Policy imposes compliance obligations on non-NIH work. We propose that the agency limit applicability to NIH-supported research or define clear boundary conditions for affiliates, tenants, leased space, and core facilities.

2. Clarify and standardize definitions

Numerous terms remain undefined or inconsistently used, including "authorized organizational representative," "biohazard," "biohazardous," "biological toxin protein," "biosafety officer," "GDMO," "primary cells that may be contaminated by adventitious agents," and "well-characterized cell lines." Clinical terms such as "shedding," "replicating," "integrating," "higher risk manipulations," and "product" also require definition.

The term "biological agent" is used inconsistently. The definition referencing bacterial, viral, fungal, or parasitic agents that cause human disease does not encompass "gene drive modified biological agents" or "RG1 wild-type agents." "Human pathogenic agent" may be more accurate where human disease is specifically intended.

The definition of "toxin" is overly broad and does not describe a toxin. Clarify toxicity characteristics such as LD50/LC50 and whether small molecule toxins are included. The definition of "laboratory research" should be revised to encompass activities that may require biosafety oversight but do not fit BSL/ABSL 1-4, e.g., arthropod containment, clinical research activities, and plants expressing human toxins.

3. Broaden the reference framework beyond Biosafety in Microbiological and Biomedical Laboratories

The Draft Policy relies heavily on Biosafety in Microbiological and Biomedical Laboratories (BMBL) for agent-specific containment. BMBL does not provide Risk Group classification and lags behind emerging research. Institutions have historically used NIH Guidelines, WHO, Public Health Agency of Canada, and other authorities.

NIH should maintain an authoritative, regularly updated Risk Group classification resource and establish a defined process and frequency for review and updates. Risk Group classification, which describes hazard, should be more strongly distinguised from Containment Level, which describes controls. We agree with the University of California Office of the President that the institutional IBCs should retain authority to assign appropriate biosafety level based on local risk assessment, available controls, and specific research.

There is also a need to clarify the NIH review process and timelines, namely what constitutes an "initial request," when NIH approval is required, and whether determinations apply to individual experiments or categories of research. Target turnaround times, completeness criteria, and an expedited pathway for urgent public health research need to be established.

Decision trees, a searchable repository of prior determinations, and pre-authorized categories for well-characterized agents, attenuated strains, and replication-defective vectors, should be provided.

4. Preserve Institutional Biosafety Committee (IBC) authority and institutional risk assessment

The IBC should remain the primary body responsible for research-specific risk assessments and containment determinations. IBC expertise requirements should be strengthened to include biosafety, public health, and infectious diseases, with animal research expertise as applicable.

Activities requiring full IBC review from those eligible for delegated review should be clearly distinguished. Requiring review of all genetically modified cells, viruses, or organisms creates a burden for routine low-risk research, particularly genetically modified arthropods and animals. There is also an inconsistency to resolve between delegated review for transgenic organisms at BSL-1/ABSL-1 and BSL-2 minimum containment for "Gene Drive Modified Organisms."

We also recommend:

- Expanding delegated review criteria for replication-incompetent or non-integrating vectors, reporter-only constructs, cell lines, primary materials, transgenic animals, and low-risk genetically modified organisms, with clear escalation triggers.

- Clarifying how exemptions operate, transition expectations, and documentation requirements. Distinguish activities outside scope, exempt from formal IBC review but subject to institutional documentation, and eligible for delegated review.
- Providing clarification on the Occupational Health and Safety Plan, including when required, expected elements, and scope of NIH oversight.

5. Revise public disclosure requirements

Public posting of IBC minutes, incident reports, and Institutional Assurances without uniform redaction standards risks security, privacy, proprietary, and reputational harm. NIH should publish a standardized redaction framework identifying information to be withheld, including sensitive facility or inventory information, security vulnerabilities, proprietary methods, and personal identifiers.

We suggest replacing institution-by-institution posting of all incident reports with a two-tier framework: NIH-reportable and high-consequence incidents reported to NIH and summarized publicly with standardized redactions. Lower-risk incidents, near misses, and anomalies should be maintained institutionally and aggregated in a centralized, de-identified database.

It is necessary to establishing clear reporting thresholds to distinguishing credible exposure or release pathways from contained anomalies. There is also a need to clarify relationships among incident reports, IBC minutes, and Institutional Assurances and to provide additional time beyond 24 hours for security-sensitive incidents or active investigations.

A continuity mechanism should be included, such as an extension during Institutional Assurance renewal review, to prevent administrative delays from interrupting compliant research.

6. Clarify containment and oversight for GDMO and environmental risks

Oversight authority for genetically modified plants must be clarified and a justification provided for exclusions. Genetically modified plants may express toxins and impact native varieties, arthropod communities, or soil microbiota.

For gene drive modified arthropods, BSL-2 minimum containment is a poor fit; the principal hazard is environmental escape, not personnel infection. Human health biocontainment must be distinguished from environmental containment and arthropod containment use levels where appropriate.

If environmental, agricultural, and animal health risks are determined to be within scope, they must be governed under the separate threshold described above rather than through an open-ended interpretation of “biohazard.”

7. Reduce administrative burden and eliminate redundancy

The implementation timeline should be extended from 6 months to a minimum of 12 months to reduce unnecessary burden. It is also essential to clarify how the institutional biosafety assurance complements existing NIH compliance certifications to avoid duplication. Providing model templates and electronic resources ahead of the effective date would be helpful.

The records-retention requirements should be specific to IBC oversight rather than tied to award financial retention. Allowing institutions to establish periodic review intervals based on risk level rather than requiring de novo IBC registration every 3 years would be appropriate.

Among other administrative concerns:

- Public posting should be limited to information necessary for transparency.
- The timing requirements should be modified for meeting minutes posting to allow flexibility based on meeting frequency.
- Substantially equivalent formats should be permitted for minutes and incident reports from institutional electronic systems and NIH should publish a machine-readable list of required fields to standardize content while minimizing duplicative work.
- Standardized IBC member training should be created and published
- The relationship of OSHA, Federal Select Agent Program, FDA, and the July 2026 USG Policy for Stopping High-Risk Life Sciences Research should be clarified to avoid duplication and conflicting determinations.

8. Establish clear biosafety oversight for clinical research

The IBC role in clinical research should complement, not duplicate, FDA and human subjects protections and, therefore, needs further clarification. Defining specific biosafety issues remaining within IBC oversight is necessary, as well as clear endpoints for oversight, such as last administration of an investigational product and an evidence-based shedding monitoring window.

Several clinical definitions also need to be provided for universal definitions of “shedding,” “replicating,” “integrating,” “higher risk manipulations,” and “product.” Adopting a hierarchy of

controls approach with standard precautions as baseline and transmission-based precautions based on hazard characteristics should be a priority.

9. Provide guidance for synthetic biology and AI-assisted research

There is a need to provide implementation guidance for de novo synthesis of genetic sequences, novel constructs without natural counterparts, and standardized biological parts conferring new properties. It is also mandatory to provide criteria and examples for IBC review, delegated review, or no review.

We also support establishing review triggers and minimum safeguards for AI/LLM-assisted biological design tied to high-consequence properties, narrowly defined to avoid impeding general computational research.

10. Required guidance documents and resources

To summarize and to support consistent implementation, NIH should make the following available before the effective date to ensure clarity, ease burden and streamline compliance:

- Comprehensive definitions and examples to assess what falls within the scope of policy
- Guidance confirming institutional IBC authority for containment and oversight
- Risk group classifications
- Templated process to request NIH determination for risk group assessment
- Guidance on reliance on posted determinations
- Searchable repository of prior determinations
- Incident report template and decision tree
- Standardized redaction guidance
- Machine-readable meeting minutes fields
- Risk assessment template beyond BMBL
- Guidance on environmental/agricultural/animal/arthropod risks
- Decision tree distinguishing scope/exemption/delegated/full review
- Delegated review template
- Standardized IBC training
- Occupational health and safety plan template
- AI/LLM and synthetic biology examples and determinations.

Thank you for the opportunity to comment. UC San Diego looks forward to continued engagement on this important Policy.

Sincerely,
Corinne Peek-Asa
Vice Chancellor for Research and Innovation
University of California, San Diego

504. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Term "Biohazard" Should Be Defined
Observation
The draft repeatedly references biohazards but does not define the term.
Real-World Implementation Impact
Biosafety professionals may develop different interpretations of what activities fall within scope.
Why This Matters
Undefined regulatory terms often become sources of implementation variability.
Recommendation
NIH should add a formal definition.

505. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Public Reporting May Discourage Near-Miss Reporting
Observation
The policy promotes both public reporting and confidential reporting mechanisms.
Real-World Implementation Impact
Personnel may be less willing to report minor events if they believe information may become publicly disclosed.
Why This Matters
Strong reporting cultures depend on trust and psychological safety.
Recommendation
NIH should clearly separate near-miss reporting from publicly posted incidents.

Incident Reporting Thresholds Require Clarification
Observation
The draft relies heavily on terms such as "any," "potential," and "significant."
Real-World Implementation Impact
These terms may trigger different reporting decisions for identical events.
Why This Matters
Consistency is difficult when thresholds are not defined.
Recommendation
Provide definitions, examples, and reporting criteria.

Public Reports Need Standardized Context
Observation
Incident reports may be publicly posted without clear contextual expectations.
Real-World Implementation Impact
Events with vastly different risk profiles may appear equivalent to external audiences.
Why This Matters

Transparency is most effective when accurate context is provided.
Recommendation
Require standardized summaries describing the nature and outcome of incidents.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

506. N/A

I am responding: On behalf of an organization

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Response-to-the-Draft-NIH-Biosafety-Policy-for-Research-Involving-Biohazards.docx

Response to the Draft NIH Biosafety Policy for Research Involving Biohazards

While we agree with the intent of the NIH's draft policy to expand their risk-based framework beyond the current policy for recombinant and synthetic nucleic acid research, we do not agree that the NIH's policies should govern **ALL** research undertaken at Universities within Australia "… **any research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with this Policy"** as Australia already has legislation, guidelines and laboratory standards that govern research in Australia.

- Both federal and state-based legislation that encompasses the Gene Technology Scheme (Gene Technology Act and Regulations) which provides a structured risk-based approval system for genetically modified organisms (GMOs) and gene drive modified organism (GDMOs).
- Strong Occupational Health and Safety laws which require all institutions to have systems in place to review and assess risks.
- The NH&MRC which is the main statutory authority of the Australian Government responsible for medical research also has policies, guidelines and codes of conduct which apply to all research.
- Laboratory design and safety standards which include Risk Grouping of microorganism and the appropriate physical containment (PC) facility guidelines which must be followed.

Compliance with Australian legislation is mandatory should take priority over NIH policy guidelines.

The University already has a properly constituted IBC for review of work with genetically modified organisms as required under Gene Technology Scheme. This scheme also included authorisation pathways for high-risk GMOs which requires approval by the IBC as well as the OGTR (Office of the Gene Technology Regulator).

The University already has a biorisk management process which assesses work with wildtype microorganisms (or material likely to contain them). The University does not have any Physical Containment Level 3 (PC3) facilities and therefore no work with Risk Group 3 or above organisms is permitted. All work with Risk Group 2 microorganisms (or material likely to contain them) is approved by the BSO and the Laboratory Biosafety Committee.

507. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: The Phrase "To the Maximum Extent Possible" Is Too Open to Interpretation
Observation
The phrase appears repeatedly throughout transparency provisions.
Real-World Implementation Impact
Institutions will apply different standards regarding disclosure and redaction.
Why This Matters
Consistency requires clearer standards.
Recommendation
Provide explicit disclosure and redaction criteria.

The Repeated Use of "Any" Creates Extremely Broad Reporting Triggers
Observation
The word "any" appears throughout multiple reporting sections.
Real-World Implementation Impact
Institutions may interpret the requirement as encompassing even trivial events.
Why This Matters
Over-reporting may obscure significant incidents.
Recommendation

Differentiate between reportable both to NIH and internally, recordable, and informational events.

The Phrase "Such As" Requires Clarification
Observation
Several reporting sections use illustrative examples.
Real-World Implementation Impact
Biosafety professionals may not know whether examples are exhaustive or merely representative.
Why This Matters
Different interpretations generate inconsistent compliance.
Recommendation
Clarify whether listed examples are illustrative or exclusive.

508. Griffith University

I am responding: On behalf of an organization

Name: Lynette Farquhar

Name of Organization: Griffith University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Griffith University supports broad, risk-based coverage of relevant biohazards. However, applying the proposed Policy to all relevant research at any institution receiving NIH funding—regardless of funding source or connection to NIH—is disproportionate and extends NIH oversight beyond the funding relationship. Mandatory requirements should be limited to NIH-funded research and activities directly supporting or materially connected to that research. For foreign institutions, NIH should establish an equivalency pathway recognising demonstrably comparable host-country statutory and institutional controls, thereby maintaining effective oversight without creating regulatory gaps or duplicating domestic requirements.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Griffith supports tiered oversight calibrated to the nature, scale and uncertainty of the risk, with federal involvement focused on higher-risk or novel NIH-supported activities and routine oversight undertaken locally. For Australian institutions, "local" oversight should include applicable Australian national regulation and accredited institutional biosafety arrangements. Australia has established IBC-based gene-technology oversight and a statutory scheme governing security-sensitive biological agents. NIH should permit these arrangements to satisfy relevant requirements through a foreign-assurance or equivalency pathway, rather than requiring duplication of US-specific structures and processes.

3. Continued utility of Risk Groups: Griffith does not recommend exclusive reliance on either Risk Groups or Biosafety Levels. The draft Policy itself recognises that RGs describe agent characteristics while BSLs address the containment appropriate to the specific work, and that the two are related but not equivalent. The final Policy should remain outcome-focused and require a comprehensive, activity-specific risk assessment. For foreign institutions, NIH should recognise equivalent domestic terminology, risk-classification and physical-containment frameworks where institutions can demonstrate that these achieve appropriate biosafety outcomes.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary adoption should be clearly distinguished from mandatory extraterritorial application. NIH may encourage organisations outside the Policy's scope to

adopt its principles and commensurate oversight voluntarily, supported by adaptable guidance, model tools and crosswalks to domestic frameworks. Voluntary compliance should not require institutions to reproduce US-specific governance, documentation or terminology. An equivalency pathway would facilitate voluntary alignment while preserving Australian regulatory responsibility for non-NIH research and avoiding the effective extension of mandatory NIH requirements to unrelated activities.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The templates provide useful structure but are highly prescriptive and create substantial administrative, redaction and publication requirements. The incident template requires detailed reporting, root-cause analysis and corrective actions, while the minutes template requires extensive protocol, risk-assessment, attendance and decision information for public posting. NIH-specific templates and public-disclosure requirements should therefore apply only to NIH-funded or materially connected activities. Incident reports and minutes relating solely to non-NIH research should not be subject to NIH publication requirements. NIH should also accept equivalent Australian institutional records, supported where necessary by a concise NIH cover sheet or mapping, rather than requiring duplicate documentation.

6. Other feedback relevant to this resource: NIH should provide dedicated guidance for foreign institutions covering: eligibility and evidence requirements for an equivalency or foreign-assurance pathway; the test for determining when research is materially connected to NIH funding; mapping of NIH requirements to Australian regulatory and containment frameworks; incident-reporting and public-disclosure expectations; and management of conflicting domestic requirements. Guidance should include worked examples for institutions with mixed NIH and non-NIH portfolios, proportionate transition arrangements and mechanisms to avoid duplicate approvals and records. NIH's existing Foreign Animal Welfare Assurance provides a useful model because it recognises applicable host-country laws and acceptable assurance standards for supported activities.

509. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Synthetic Biology Reviews May Become Overly Conservative
Observation
The policy assumes introduced sequences retain their original function.
Real-World Implementation Impact
Investigators may face containment requirements disproportionate to actual risk.
Why This Matters
Risk assessment should remain evidence-based and proportionate.
Recommendation
Clarify how empirical evidence may modify initial assumptions.

Gene Drive Review Criteria Need Greater Specificity
Observation
The policy references uncertainty and environmental impacts without thresholds.
Real-World Implementation Impact
Biosafety professionals may differ substantially in review expectations.
Why This Matters
National consistency requires clearer criteria.
Recommendation
Provide examples and decision frameworks for evaluating uncertainty and environmental risk.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

510. Ericka E. Pearce

I am responding: On behalf of myself

Name: Ericka E. Pearce

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): arlington

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Overall Assessment and Recommendation
Observation
The transition from a prescriptive framework to a broader risk-based framework is appropriate and forward-looking.
Real-World Implementation Impact
The primary challenge faced by biosafety professionals will be interpreting broad terms, implementing new governance structures, applying novel reporting requirements, and achieving consistency with limited implementation guidance.
Why This Matters
The success of the policy will depend less on the principles it establishes and more on whether biosafety professionals can implement those principles consistently.
Recommendation
NIH should accompany the final policy with:
• Definitions;
• Decision trees;
• FAQs;
• Model governance structures;
• Risk assessment examples;
• Transition guidance;
• Reporting thresholds; and
• Implementation toolkits.
These resources would significantly improve consistency, transparency, and successful implementation across the research enterprise.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

511. Harvard Medical School

I am responding: On behalf of an organization

Name: Rebecca Ryan Caruso

Name of Organization: Harvard Medical School

Type of Organization: Academic Institution

Role: Other

Role - Other: Director, IBC

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Harvard Medical School

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Harvard-Biosafety-Comment-Letter.pdf

HARVARD MEDICAL SCHOOL | COMMITTEE ON Microbiological Safety

Comment on NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

To Whom It May Concern:

I write on behalf of Harvard University in my capacity as Director of Harvard's IBC (COMS) to submit the following comments in response to the National Institutes of Health (NIH) effort to modernize biosafety oversight and to create a risk-based framework that extends beyond recombinant and synthetic nucleic acid research. We strongly support rigorous biosafety practices in research, though we believe that any final policy would benefit from greater precision in its definitions, clearer boundaries of authority, and additional implementation guidance prior to the finalization.

As a member of the Association of American Universities, COGR, and ABSA International, Harvard generally endorses their comments and recommendations, except as noted below. In general, we support revising the draft policy, allowing an additional comment period, and adopting a phased, 24-month implementation period so institutions can update their policies, training, and oversight systems. We share the associations' concerns about scope, definitions, regulatory clarity, and operational feasibility and offer the following comments to strengthen the proposal.

Policy Scope (Section II). The draft policy seeks to include "all biomedical research, in laboratory settings…involving biohazards…[with] known or potential risk to human health." While the "risk to human health" implies RG2/BSL-2 research and above, other sections of the draft policy expand potential applications to BSL-1 research, naturally occurring mutants of low-risk organisms, environmental samples with "adventitious agents," non-pathogenic recombinant constructs, and toxins not extracted from their natural environments. We urge you to clarify that field research, arthropod containment, and plant containment is outside the scope of the draft policy. Additionally, for biological agents that pose risk to animal health but are not known to cause disease in humans, we urge NIH to define the threshold for review and oversight.

Roles and Responsibilities (Section III). The NIH draft policy requires the review of broadly conceived emerging, novel and zoonotic agents, which will require NIH consultation for routine determinations currently managed by institutional biosafety programs and institutional biosafety committees (IBCs). In addition to tightening these definitions, as recommended elsewhere in this letter, we urge NIH to preserve IBC authority for making containment determinations whenever possible.

NIH should clarify its authority for "determining the appropriate containment level for emerging, novel, or zoonotic biological agents for which the RG classification or containment level is not available in the BMBL." To that end, we recommend that only organisms that meet the definition of RG3/RG4 or BSL-3/BSL-4 research be subject to this requirement; the assignment of containment levels for organisms meeting the definition of RG1 and RG2 should remain within the purview of the IBC. As part of these clarifications, we urge NIH to detail how institutions should manage existing risk assessments for organisms that lack risk group designations or biosafety level recommendations when IBCs have already assigned minimum containment, define the risk group levels referenced in criteria requiring NIH approval of containment, and limit retrospective review to organisms classified as RG3 or RG4, or for research requiring BSL-3 or BSL-4 containment.

The draft policy calls for NIH to publish approved lower-containment determinations for research involving wild-type or genetically modified RG3 or RG4 agents but does not extend this requirement to emerging, novel, zoonotic, or GDMO agents. We recommend including those determinations in a searchable resource similar to the Public Health Agency of Canada's *ePathogen* database. Containment levels established by other federal agencies, such as the Centers for Disease Control and Prevention, should require only notification to NIH for inclusion in the list, not separate NIH approval. NIH should also establish a process for periodically reviewing listed agents against new scientific literature and public health data and publish proposed changes for comment before adoption.

To focus on IBC activities appropriately, we recommend that the final policy establish clear, broad exemptions and expedited review categories for well-characterized, low-hazard work, such as non-pathogenic host strains, well-characterized cell lines, and low-risk inserts. The policy should also specify when delegated review must be escalated to the full committee and clarify when an IBC may assign containment levels and approve research involving agents not listed in the BMBL. Because the agents included in the BMBL vary by edition and may be removed from later editions, the BMBL should serve as a reference rather than the sole basis for determining containment. IBCs should also be permitted to use relevant scientific literature when assigning containment levels for agents that meet RG1 or RG2 criteria.

For research with non-select agent toxins and self-aggregating proteins (not prions), NIH should allow delegated review. (See comments regarding "toxin"-defining criteria and potential removal from scope.) Additionally, the section requiring IBC review and approval before initiation should be narrowed with the addition of the following language in parentheses: "Research with primary cells that may be contaminated [with RG3 or RG4] agents [or agents requiring BSL-3 or BSL-4 containment]."

Additionally, the NIH policy should clarify when delegated review is allowed for "minor amendments to previously IBC approved submissions" vs new projects or projects going through subsequent de novo review. We recommend allowing delegated review for all protocols and amendments not explicitly requiring IBC review and approval before initiation. We also support further clarification of the following language in this section:

- Research with "genetically modified RG1 biological agents" is subject to the policy when wildtype RG1 agents are not. Most recombinant experiments with RG1 organisms are exempted or fall under III-E of the current NIH Guidelines. A common example is cloning or expressing to human/animal genes in non-pathogenic *E. coli* or integration of a fluorescent tag. Since most recombinant experiments with RG1 agents do not elevate risk, we recommend changing to only "genetic modifications in RG1 organisms expected to lead to pathogenicity or production of a toxin capable of negatively impacting human health such that elevated containment is required".
- The policy implies that all research involving plasmids (even outside of an organism) now requires registration. We recommend the following language requiring registration of these systems only when used in organisms or cells: "Research with plasmids or replication-incompetent, non-integrating viral vectors expressing reporter or low-risk transgenes."
- Remove "Research with well-characterized cell lines" from delegated review because the policy covers cell lines only when they include a biohazard (Section IV-3).

Risk Assessment (Sections III, IV, V). The risk group classification provides a starting point for determining containment as it relates to personal and environmental risk, although the BMBL does not include that category. Instead, the current NIH Guidelines act as the reference point for risk group classification. We urge NIH to add a risk group table to the policy and to determine if an agent qualifies as a "biohazard" and a "risk to human health" for inclusion within the policy scope. If retained within the policy, NIH should clarify how toxins and proteins will be classified and specify who holds authority to assign containment for this category and how incidents involving toxins and proteins are to be reported,

given that these agents are handled, shipped, and disposed of as chemicals and are not assigned risk groups or biosafety levels.

We also urge NIH to revisit the synthetic-biology framework and the influenza provision in consultation with the stakeholder community. Although Section V-C appropriately discusses gene function and possible synergy, it emphasizes the highest risk group of source organisms, the percentage of genome contributed by each source, and an assumption that sequences function as they did in their original host. These are not reliable general predictors of biological risk, as their function depends heavily on regulatory, cellular, genomic, and ecological context. Similarly, the influenza provision requires containment to correspond to the source contributing the majority of viral segments. Influenza phenotype is not determined by segment counting. A minority segment or a small number of mutations can affect receptor binding, host adaptation, polymerase activity, tissue tropism, pathogenicity, or transmissibility. For these reasons, we urge that any containment on influenza should be based on the specific construct, phenotype, and protocol.

Emerging, Novel, and Zoonotic Agents (Sections III-B, III-D, IV-1). As drafted, the NIH requirement for containment determinations for emerging, novel, and zoonotic agents – which commonly lack established risk group classifications and biosafety levels – poses a unique challenge for institutions. Many organisms, particularly those used at BSL-1 based on institutional risk assessment determinations, are not listed in the BMBL, making it unclear when NIH review would be required before work could begin. To resolve this ambiguity, and minimize project delays and inconsistent determinations, NIH should develop a national risk group or containment database and publish determinations for agents lacking established containment. That said, it is our strong recommendation that NIH allow IBCs to determine an appropriate containment level based on risk assessment when there is no clear evidence of significant risk to human health and where agents do not meet the definition of RG3-RG4 or require BSL-3 or BSL-4 containment.

Also, the NIH draft policy does not contain a clear distinction between “novel” vs “genetically modified" agents. We recommend either uniting or further separating these definitions and retaining IBC review and approval with few exceptions. NIH should define criteria for their involvement in setting containment based on risks, not simply based on the “agent or organism not existing in nature, [being] deliberately designed, and possibly derived from multiple, different natural or synthetic sources.” Examples would be single-cycle replicon systems that lack structural protein genes or an agent modified to serve as a vaccine candidate.

Incident Report and IBC Provisions (Sections III-B and III-C). While we appreciate and support institutional consistency and transparency, some of the new requirements could substantially increase burden while providing limited risk reduction. In general, we urge NIH to ensure reporting is tiered and risk based, with a clear separation between voluntary learning reports and enforcement systems; limit who may access submitted information that includes security-sensitive, proprietary, clinical, personnel, and reputational information; clarify whether submissions could become subject to disclosure or legal process; publish aggregate lessons learned back to the biosafety community; and, monitor these changes for impacts to safety and de-incentivization in reporting

On the IBC minutes, we recommend that the incident reporting section in the template be sufficient for posting of incidents, with the redaction of PI names and laboratory identifiers, and that the requirement related to the review and inspection reports for every protocol be limited to discussion or notation only when significant deficiencies are noted. We also recommend that non-IBC members be allowed to remain anonymous to ensure continued public participation and engagement.

Further, the policy should confirm if the incident reporting template is to be used for urgent, 24-hour reporting, with the understanding that most sections would be incomplete in an initial report. NIH should provide an IBC vs. NIH authority table for incident reporting (as an example, see Appendix A). The

boundary between institutional handling and NIH notification is currently unclear and spread across narrative text.

Nexus with the Policy for Stopping High Risk Life Sciences Research, While we support NIH's stated intention to develop a more coordinated interagency policy, we are concerned that the draft NIH policy is incongruent with the Policy for the Stopping High Risk Life Sciences Research (High-Risk Policy), with scope and definitions that differ significantly. At many institutions, including Harvard, IBCs serve as the primary reviewing body for biological research and the principal referral mechanism to Institutional Review Entities (IRE) for assessment of dangerous gain of function (DGOF) research. Because of this relationship, the IBC or a subset of IBC members may also act as the IRE. Additionally, agencies and institutions attempting to implement the Policy for Stopping High-Risk Life Sciences Research have previously relied on the NIH Guidelines to help assess experimental risk of formerly DURC/PEPP and now DGOF. A similar expectation will likely exist for the new NIH Biosafety Policy to set a standard for reviewing research and anticipating risk. Unlike the broad geographic scope of the High-Risk Policy, the Biosafety Policy applies to biomedical research "in laboratory settings." Thus, the IBC will likely need to expand its oversight to cover all life sciences research, including that outside of a lab setting, to meet these conflicting requirements. In addition, determining how to evaluate research that appears permissible under the draft NIH policy but may be prohibited or restricted under the High-Risk Policy begs for the two to be deconflicted.

Specifically, the draft NIH policy and the USG High-Risk Policy both add review bodies, reporting duties, and increased scope over life sciences research, and they reach many of the same projects. Institutions need to know how these policies interact so one project is not reviewed, reported, and audited in parallel by overlapping bodies with different timelines and standards. A single, harmonized reporting pathway would reduce burden without reducing oversight. As part of this effort, NIH should consider the creation of a decision tree to help identify when an agent falls under both the NIH policy and the DGOF/IROC framework, particularly when an experiment substantially increases the agent's dangerous biological properties. The decision tree should clarify principal investigator and IBC responsibilities and provide standardized criteria and examples.

Additionally, under the High-Risk Policy, a principal investigator must attest to having undergone institutional review of their life sciences research at the point of a grant application to determine applicability of that policy. This poses challenges related to the NIH policy that should be addressed, as both policies' requirements are considerations for NIH-sponsored research. For example, the lack of overlap between the IBC and IRE purview presents a problem for assessing biosafety risks and mitigation strategies, if the IBC would have previously led the review process and referred to the IRE. Similarly, if the research is inclusive of agents that now require NIH review and approval before containment can be set, the principal investigator is unlikely to be able to submit the grant in time for such an assessment to conclude, inhibiting research funding. Additionally, the language in these policies encompasses work of different risk/benefit profiles with clear biomedical importance. This is inclusive of research necessary for the study of the mechanisms of action and resistance to treatments and preventative measures against infectious disease. Yet the risk assessment aspects of the policies do not align in terms of how such research may proceed. With strict interpretation, the policies may also inhibit the study of naturally arising variants with changing genetic sequences or protein functions, which are critical for understanding how treatments and prevention strategies can be effectively implemented.

Definitions. Similar to the associations, key operational definitions, such as biohazard, emerging agent, novel agent, zoonotic agent, genetic modification, and toxin, require additional specificity to ensure that they do not unintentionally expand the scope of the policy to encompass routine and low- risk activities. Specifically, we recommend the following additions and clarifications:

- *Animals/ Animal Work (addition)*: Since the proposed policy is focused on human health risks, we recommend a new definition of animals/animal work as follows to clarify what oversight remains for human health studies involving animal models: "Organisms in the Kingdom Animalia, excluding whole arthropods, arthropod eggs, and parasitic worms; includes whole animals and materials derived from animals."
- *Biohazards*: We recommend clarification to ensure consistency in the application of the criterion throughout the policy and to support a clear nexus to human disease. Specifically, as research focused on animals, plants, and arthropods may result in secondary effects on human health, the NIH should clarify when these types of work are covered under the policy. One example would be gene drive experiments that affect arthropod vectors of human disease such as genetic modification of mosquitos to reduce malaria transmission. Additionally, NIH should provide concrete examples of activities that are in scope and out of scope, particularly for animal pathogens, agricultural and plant pathogens, environmental organisms, and prions and other self-aggregating proteins, as these categories sit at the margin of the human-disease criterion, and defined examples will permit institutions to be consistent in how these materials are classified. Finally, the term "parasite" could be interpreted to parasites possibly leading to human disease (e.g., ticks, mosquitos). We suggest instead "protozoan organisms considered parasitic to humans."
- *De Novo Review (added).* We recommend the following definition of De Novo Review to be added to the policy: "An IBC submission of a registration that may be new or have been reviewed and approved previously by an IBC.
- *Emerging Agent or Organism*. We urge clarification of the draft policy's definition of emerging agent or organization to link back to "risk to human health", and it should be supported by NIAID's list of emerging diseases. Specifically, the definition should define how much an organism needs to deviate from known species before it is considered "emerging" or "new" under the policy. Typically, pathogens are considered "emerging" when they increase in incidence, expand geographically, acquire new host ranges, or change epidemiologically.
- *Genetic Modification*: We recommend that NIH clarify whether the policy applies to transient expression systems, engineered phage, and other low-risk work that creates no reasonable human-health hazard. We suggest that genetic modification should be one factor in risk assessment, not an automatic indicator of elevated risk. The definition unintentionally classifies naturally evolving organisms as genetically modified. Additionally, mutations acquired through passaging and exposure to chemicals/radiation should not constitute "genetic modification" as this could occur in nature. The following line should be removed from the definition: "The introduction into cells, organisms, or viruses of stable alterations into the genome by passaging, reassortment, chemical or radiological means." It is unclear if the definition also applies to RG1/BSL-1 experiments, as its inclusion in the category of "biohazard" is inconsistently applied throughout the document.
- *Novel Agent or Organism*: We suggest that "novel agent" or organism should be defined by biological properties and plausible hazards, not simply by whether an organism exists in nature. The NIH definition should distinguish between something that is "novel" vs "genetically modified". For example, if a viral vector is considered "genetically modified" or a "novel agent". If a "novel agent" is defined by a percentage of its genome or protein structure that differs from an organism that exists in nature, NIH also should further expand the examples, such as "chimeras" and "organisms generated by synthetic biology in conjunction with artificial intelligence."
- *Prions and Self-aggregating Proteins*: Not every self-aggregating protein is infectious, transmissible, or capable of causing neurodegenerative disease. Infectious PrP prions, protein-seeding models, and noninfectious aggregation research represent different hazards and should not automatically be treated as of equivalent risk. We suggest that NIH clarify how they will

determine if proteins “cause neurodegenerative disease”. Several proteins are associated with such disease, but it is unclear if they “cause” the disease. NIH should provide examples and criteria to support consistent determination, and it should consider a process for later classification of proteins with currently unknown or incompletely characterized functions.

- *Toxins*: NIH should remove toxins and proteins from the policy since many toxins of risk to humans meet the definition for chemicals of acute toxicity and have existing requirements for handling under OSHA (29 CFR 1910.1450). If retained, we suggest the following revisions: reference the definition of a toxin used by the Federal Select Agent Program and provide examples; eliminate the vague "causes harm in humans" in favor of objective criteria, given that harm depends on dosage; incorporate the LD50 or similar threshold-based criteria to determine whether a substance meets the definition of a biological toxin; provide exclusion criteria consistent with the Federal Select Agent Program, such as toxins in their natural environment; and clarify how uncharacterized proteins from venomous animals should be handled. In drug-discovery research with venomous animals, venoms are extracted (proteins or genetic material) from their venom-producing glands. This means that physiologically “normal” proteins/genes and venom (toxic) proteins/genes will be extracted in the same experiment. This imposes a requirement to conduct purification, fractionation, analytical characterization, and computational identification of all novel compounds before any biological activity assessment can be conducted. A retrospective, non-punitive process should be established for classification of unknown proteins later determined to be “toxins” through experimentation.
- *Zoonotic*: We would redefine the term as follows: “An agent with known transmission from animals to humans documented to cause human disease as observed through clinical case presentation.” NIH should provide examples to support interpretation.

We appreciate NIH’s community engagement efforts and believe that our suggestions will help meet our shared goal of a modernized biosafety oversight framework that is both effective and practicable for institutions. Thank you for this opportunity to comment.

Sincerely,

[redacted]

Rebecca Ryan Caruso
Director, Harvard Committee on Microbiological Safety

Appendix A. Incident Reporting Matrix

A single table — incident category, threshold, responsible body, timeframe, posting requirement — would drive consistency across institutions and is a useful implementation aid NIH could supply as part of an implementation guidance document. The illustrative table below is an example that reflects our reading of the draft. Entries marked "To be specified" identify where the draft is silent or ambiguous; those gaps are the substance of our request.

Incident category	Reporting threshold	Authority	Timeframe	Public posting
Laboratory-acquired infection	Any confirmed or suspected LAI	NIH and IBC	24 hours	To be specified
Loss of containment with potential community risk	Any release with potential for exposure outside the facility	NIH and IBC	24 hours	To be specified
BSL/ABSL-3 or -4 incident	All incidents, regardless of exposure or injury	NIH and IBC	24 hours	To be specified
BSL/ABSL-2 incident with medical treatment	Agent-specific treatment beyond basic first aid — term requires definition	NIH and IBC	24 hours	To be specified
BSL/ABSL-2 exposure, first aid or prophylaxis only	Institutional record; no NIH notification	IBC only	Institutional	To be specified
Animal bite or scratch, no agent exposure	Institutional record; no NIH notification	IBC only	Institutional	To be specified
Spill within containment, no exposure	Institutional record; threshold not addressed in draft	IBC only — to be confirmed	Institutional	To be specified
Shipping or transport deviation	Not addressed in draft	To be specified	To be specified	To be specified
Toxin or protein incident (no RG/BSL assigned)	Not addressed in draft	To be specified	To be specified	To be specified

512. Providence

I am responding: On behalf of an organization

Name:

Name of Organization: Providence

Type of Organization: Healthcare Institution

Role: Healthcare Provider

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: 2026_10_19_NIH-Biosafety-Policy-Comments.pdf

Description: See attachment.

Providence
1801 Lind Avenue SW
Renton, WA 98057
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October 19, 2026

The Honorable Lyric Jorgenson, PhD
National Institutes of Health
Office of Science Policy
6705 Rockledge Dr., Suite 630
Bethesda, MD 20892

RE: NOT-OD-26-112; Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards

Dear Acting Associate Director Jorgenson:

On behalf of Providence, thank you for the opportunity to provide feedback in response to the National Institutes of Health's request for information on the Draft NIH Biosafety Policy for Research Involving Biohazards published on the NIH website on August 19, 2026.

Providence is a nonprofit health system dedicated to a holistic approach to medicine that employs not only the most advanced treatments to improve outcomes, but also puts compassion and humanity at the heart of every interaction. Together, our 125,000 caregivers (all employees) serve in 51 hospitals, 1,014 clinics and a comprehensive range of health and social services across Alaska, California, Montana, New Mexico, Oregon, Texas and Washington. Guided by our Mission to serve all, we are committed to high-quality, compassionate health care for everyone – regardless of coverage or ability to pay. We help people and communities benefit from the best health care model for the future – today.

Research is vital to Providence's mission of service, compassion and healing. Our research supports that mission with groundbreaking research and evidence-based solutions — keeping more people healthy and making our services more convenient, accessible and affordable for all.

In this letter, we offer comments on the following areas of the proposed rule:

- Research Involving Primary Human Specimens
- Research Involving Established Human Cell Lines
- Research Involving Genetically Modified Cells and Viral Vectors
- IBC Documentation, Public Disclosure, and Protection of Confidential Research Information
- Avoiding Duplicative Oversight and Unnecessary Administrative Delays

Research Involving Primary Human Specimens

Relevant provision: Section IV-2 — Research Requiring IBC Review and Approval Before Initiation

The draft policy identifies research involving primary cells that may be contaminated by adventitious agents as requiring IBC review and approval before initiation.

This provision could encompass an extraordinarily broad range of biomedical research, including routine laboratory studies involving peripheral blood mononuclear cells (PBMCs), lymphocytes, human tumor biopsies, surgical specimens, tumor-infiltrating lymphocytes (TILs), primary tumor cultures, and patient-derived organoids.

These materials are essential to contemporary translational cancer research and are routinely handled under established institutional biosafety practices, including appropriate BSL-2 precautions and universal precautions for potentially infectious human specimens.

Although primary human specimens can contain adventitious infectious agents, the mere possibility of such contamination should not automatically require separate protocol-specific review by the full IBC.

It is important to distinguish between routine handling of potentially infectious human specimens and experimental procedures that intentionally propagate infectious agents, increase exposure risks, or introduce additional biological hazards

Recommendations

Establish Streamlined Institutional Review Mechanisms

NIH should permit institutions to approve routine collection, processing, culture, and analysis of primary human specimens through institution-wide or laboratory-specific biosafety registrations.

Such approvals could cover defined classes of specimens and experimental procedures rather than requiring separate IBC submissions for every scientific research protocol.

Permit Delegated Review of Routine Human Specimen Research

Routine research involving primary human tissues and cells should be eligible for delegated review by an institutional biosafety officer or designated IBC member when established containment procedures are appropriate and no additional biological hazards have been identified.

Reserve Full IBC Review for Activities Involving Increased Biological Risk

Full IBC review should be required when experimental procedures introduce hazards beyond those associated with routine specimen handling, including intentional propagation of infectious agents, modifications increasing pathogenicity or transmissibility, or procedures requiring higher levels of containment.

Clarify the Meaning of “may be Contaminated by Adventitious Agents”

Without additional clarification, this language could encompass virtually all primary human specimens. NIH should specify how institutions should evaluate the likelihood and consequences of contamination and whether routine BSL-2 practices adequately mitigate the associated risks.

Suggested Policy Language

"Research involving routine collection, processing, culture, or analysis of primary human cells and tissues, including blood-derived cells and tumor specimens, may be reviewed and approved through an institutional biosafety registration or delegated review process when the activities are conducted under established containment practices and do not involve intentional propagation of infectious agents or other procedures introducing additional biological hazards.

Separate protocol-specific IBC approval shall not be required for activities covered by an approved institutional or laboratory-specific biosafety registration, provided that the activities remain within the scope of the approved risk assessment."

Research Involving Established Human Cell Lines

Relevant provision: Section IV-3 — Research Eligible for Delegated Review

The proposed policy appropriately recognizes that research involving well-characterized cell lines may be eligible for delegated review.

This is an important distinction because established human cell lines are among the most widely used experimental systems in biomedical research.

Cancer research laboratories routinely employ established tumor cell lines for studies of antigen expression, immune recognition, tumor biology, drug sensitivity, vaccine development, and mechanisms of resistance to immunotherapy.

These studies may involve hundreds of experimental variations using the same cell lines without materially changing the underlying biosafety risks.

Requiring repeated biosafety submissions for routine experimental modifications would add administrative burden without necessarily improving laboratory safety.

Recommendations

Establish a Clear Definition of Well-Characterized Cell Lines

NIH should clarify that well-characterized cell lines include established human and animal cell lines with documented identity, provenance, and appropriate biosafety characterization.

The definition should not depend solely on whether a cell line was obtained from a commercial repository. Research laboratories frequently develop and maintain extensively characterized cell lines that are not commercially distributed.

Permit Laboratory-wide Registration of Established Cell Lines

Institutions should be permitted to approve the use of defined categories or collections of established cell lines under a single laboratory biosafety registration.

Addition of another cell line with an equivalent risk profile should not automatically require a new IBC protocol.

Exempt Routine Experimental Changes from Repeated Review

Changes in culture media, cytokine exposure, drug treatment, antigen expression analysis, immune-cell coculture, and similar procedures should not require additional IBC approval unless they materially alter the biological hazard.

Differentiate Established Cell Lines from Cell Lines with Specific Hazards

Full IBC review should remain available for cell lines containing replication-competent pathogens, producing infectious agents, or presenting other identifiable risks requiring enhanced containment.

Suggested Policy Language

"Research involving well-characterized established cell lines may be conducted under laboratory-specific or institutional biosafety registrations approved through delegated review.

Routine experimental modifications, including changes in culture conditions, noninfectious treatments, and cellular assays, shall not require additional IBC review unless they introduce new biological hazards or materially alter the approved biosafety risk assessment.

Institutions may establish procedures for adding cell lines with equivalent biosafety characteristics to an existing approved registration."

Research Involving Genetically Modified Cells and Viral Vectors

Relevant provisions: Sections IV-2, IV-3, and V-B

The proposed policy requires IBC review for research involving genetically modified cells, viruses, and organisms while allowing delegated review for certain lower-risk experiments, including those involving genetically modified Risk Group 1 agents and replication-incompetent, nonintegrating viral vectors expressing low-risk transgenes.

I support the concept of tiered oversight. However, the proposed distinctions may not adequately reflect the diversity of genetic engineering methods routinely used in contemporary biomedical research.

Genetic modification is now a standard laboratory technique employed to investigate gene function, tumor antigen expression, immune recognition, cellular differentiation, and mechanisms of disease.

Examples include expression of tumor-associated antigens or noncanonical proteins in established cell lines, introduction of T-cell receptors into cultured lymphocytes, CRISPR-mediated gene knockout or modification, transient expression of reporter genes, use of replication-defective lentiviral or retroviral vectors, and genetic modification of tumor cells for studies of immune recognition.

These approaches have markedly different biological risk profiles.

The use of genetic modification alone should not determine whether a protocol requires full IBC review. Instead, the level of oversight should reflect the actual hazards associated with the modified cells, vectors, expressed products, and experimental procedures.

Recommendations

Expand Delegated Review to Additional Categories of Low-risk Genetic Modification

NIH should consider extending delegated review eligibility to well-characterized replication-defective integrating vectors, including selected lentiviral and retroviral vector systems, when the overall risk assessment supports this approach.

Although integration introduces additional considerations, it does not necessarily justify full IBC review for every experiment.

Differentiate Genetic Modifications According to their Biological Consequences

The risk assessment should consider whether a modification increases pathogenicity or transmissibility, produces an infectious or replication-competent agent, alters host range or tissue tropism, introduces a

toxin or other hazardous gene product, or otherwise increases risks to laboratory personnel or the environment.

Routine expression of nonhazardous proteins, reporters, or tumor antigens should generally qualify for streamlined review.

Permit Platform-based Approvals for Commonly Used Vector Systems

Institutions should be able to approve defined vector platforms and associated laboratory procedures through a single biosafety registration.

For example, a laboratory routinely using a characterized replication-defective lentiviral vector platform to express nonhazardous proteins should not require an entirely new IBC protocol for each transgene, provided the new construct does not materially change the biosafety risk assessment.

Establish a Streamlined Amendment Process

Minor changes involving nonhazardous transgenes, reporter constructs, or experimental targets should be eligible for administrative or delegated review.

Full IBC review should be reserved for modifications that materially increase biological risk.

Distinguish Genetically Modified Producer Cells from Final Investigational Products

In cancer vaccine and cell therapy development, genetically modified cells may be used to manufacture products that do not themselves contain viable genetically modified cells or replication-competent vectors.

NIH should clarify that biosafety assessments of manufacturing activities and final products should be based on their respective hazards.

A final nonreplicating, nonintegrating, cell-derived vaccine product should not automatically be assigned the same biosafety risk classification as the genetically modified cells used during its manufacture.

Suggested Policy Language

"Research involving genetically modified cells or viral vectors shall be assigned to an appropriate level of oversight based on the biological characteristics of the modified material, the properties of the introduced genetic elements, the potential for replication or dissemination, and the risks associated with the proposed experimental procedures.

Delegated IBC review may be used for research involving well-characterized replication-defective vector systems and genetic modifications that do not materially increase biological hazards, when supported by a documented institutional risk assessment.

Institutions may approve established genetic modification platforms through laboratory-specific biosafety registrations. Changes in transgenes or experimental constructs that do not materially alter the approved risk assessment may be addressed through streamlined amendment procedures."

IBC Documentation, Public Disclosure, and Protection of Confidential Research Information

Relevant provisions: Delegated IBC Review, IBC Meeting Minutes, and Public Disclosure Requirements

The proposed NIH Biosafety Policy would require actions approved through delegated review to be reported "in full" at the next scheduled Institutional Biosafety Committee meeting and documented in the meeting minutes. The policy also provides for public posting of approved IBC meeting minutes, subject to allowable redactions.

While transparency and institutional accountability are important objectives, these provisions raise significant concerns regarding the disclosure of unpublished scientific research, intellectual property, proprietary research methods, confidential personnel information, and laboratory security-sensitive information.

These concerns are particularly important for translational biomedical research institutions conducting innovative research in cancer immunotherapy, vaccine development, genetic engineering, and investigational therapeutics, frequently in collaboration with biotechnology companies and pharmaceutical partners.

IBC protocols may contain detailed descriptions of experimental approaches, unpublished discoveries, novel constructs, proprietary manufacturing methods, and research strategies that have not yet been patented or publicly disclosed.

Public disclosure of such information could compromise intellectual-property protection, interfere with scientific publication, undermine contractual confidentiality obligations, and discourage academic-industry collaborations.

In addition, IBC records may contain information concerning laboratory locations, biological agent inventories, occupational-health considerations, personnel responsibilities, and security measures that should not be disclosed publicly.

The requirement that delegated approvals be reported "in full" is particularly concerning because it is unclear whether this refers to a complete description of the underlying research protocol or a complete accounting of the IBC's review and approval actions.

NIH should explicitly distinguish between complete internal documentation of biosafety decisions and the information necessary for meaningful public transparency.

Recommendations

Define the Minimum Information Required in Publicly Posted IBC Minutes

NIH should establish clear and consistent standards identifying the information necessary to document IBC oversight and institutional accountability.

Public records should document the committee's actions, including quorum, recusals, risk determinations, approval conditions, and voting outcomes, as applicable, without requiring disclosure of confidential protocol-level scientific information.

Clarify the Meaning of Reporting Delegated Approvals "in Full."

NIH should specify that this requirement refers to a complete accounting of delegated review decisions, including the nature of the activity, applicable risk classification, approval determination, and any conditions of approval.

It should not require public disclosure of complete research protocols, experimental methods, genetic constructs, unpublished findings, or other confidential scientific information.

Establish Explicit and Consistent Redaction Standards

The final policy should authorize appropriate redaction of information involving unpublished scientific discoveries, patentable inventions, intellectual property, trade secrets, proprietary experimental methods, confidential sponsor information, personally identifiable information, occupational-health information, biological agent inventories, sensitive laboratory locations, facility vulnerabilities, and security controls.

NIH should provide clear guidance to promote consistent implementation across institutions and minimize uncertainty regarding permissible redactions.

Establish a Reasonable Period for Public Posting

The requirement for immediate posting of approved IBC minutes could create substantial administrative and compliance burdens.

Institutions require sufficient time to conduct appropriate privacy, intellectual-property, security, legal, and communications review before releasing documents publicly.

NIH should establish a reasonable, defined posting period following approval of meeting minutes rather than requiring immediate publication.

Permit Standardized Public Summaries while Retaining Complete Internal Records

NIH should permit institutions to prepare standardized public summaries of IBC proceedings that provide meaningful information about biosafety oversight without disclosing confidential or security-sensitive information.

Complete, unredacted meeting minutes, protocol submissions, risk assessments, and supporting documentation should be maintained internally and made available to NIH and other authorized oversight authorities as required.

This approach would preserve regulatory accountability while reducing the risks associated with public disclosure.

Suggested Policy Language

"Institutions shall maintain complete internal records of IBC proceedings, delegated reviews, risk assessments, approval determinations, and associated supporting documentation.

Publicly available IBC records may consist of appropriately redacted meeting minutes or standardized summaries that document committee actions, risk classifications, approval decisions, conditions of approval, quorum, recusals, and voting outcomes, as applicable.

Reporting delegated approvals 'in full' shall require a complete accounting of the review actions and determinations, but shall not require public disclosure of complete research protocols or confidential scientific, proprietary, personnel, occupational-health, or security-sensitive information.

NIH shall establish uniform standards for permissible redactions and a reasonable period following approval of IBC minutes for institutions to complete appropriate confidentiality, intellectual-property, privacy, legal, and security reviews before public posting.

Complete, unredacted records shall be retained by the institution and made available to authorized oversight authorities as required."

Avoiding Duplicative Oversight and Unnecessary Administrative Delays

An overarching concern is the potential for duplicative oversight across institutional review systems.

Biomedical research institutions already maintain established processes involving Biosafety Committees, occupational-health programs, Institutional Review Boards, Institutional Animal Care and Use Committees, and other research compliance offices.

For studies involving investigational therapies, additional oversight is provided through FDA requirements and institutional clinical research governance.

Although these systems serve different purposes, unnecessary duplication of administrative review should be avoided.

NIH should explicitly encourage coordinated review and recognition of existing institutional risk assessments.

In addition, NIH should establish clear expectations for timely delegated review and distinguish between modifications that require prospective approval and routine changes that can be documented within an existing approved protocol.

NIH should provide model umbrella registrations, model public summaries, redaction examples, and implementation guidance before the policy becomes effective.

Conclusion and Requested NIH Actions

The proposed NIH Biosafety Policy presents an opportunity to modernize biosafety oversight while improving the efficiency of biomedical research.

Providence supports NIH's objective of strengthening biosafety through a scientifically grounded, risk-based framework. However, achieving that objective requires distinguishing research involving meaningful biological hazards from routine laboratory procedures conducted under well-established containment practices.

We encourage NIH to incorporate the following principles into the final policy:

1. Permit institution-wide or laboratory-specific biosafety registrations for routine studies involving primary human specimens.
2. Expand delegated review eligibility for low-risk research involving human tissues, established cell lines, and well-characterized genetic modifications.
3. Allow platform-based approvals for established cell culture and viral vector systems.
4. Require additional IBC review only when experimental changes materially alter the underlying biosafety risk assessment.
5. Distinguish the risks associated with genetically modified manufacturing systems from those associated with final investigational products.
6. Establish clear standards for public disclosure of IBC proceedings, including minimum reporting requirements, permissible redactions, and reasonable timelines for public posting.
7. Permit standardized public summaries of IBC decisions while requiring institutions to retain complete, unredacted records internally, thereby protecting unpublished scientific discoveries, intellectual property, confidential personnel information, and laboratory security-sensitive information.

8. Promote coordination with existing institutional and federal oversight systems to avoid unnecessary duplication and delays.

NIH has an opportunity to establish a modern framework that directs regulatory attention and institutional resources toward research presenting meaningful biological risks while allowing routine biomedical research to proceed efficiently under established safety practices.

The success of this policy should ultimately be measured not by the number of protocols subjected to review, but by its effectiveness in protecting research personnel, patients, and the public while enabling responsible scientific innovation.

Thank you for the opportunity to provide feedback on the Draft NIH Biosafety Policy for Research Involving Biohazards. We hope you find our input informative. For more information about the views we have expressed, please contact our government affairs team at anne.mitchell@providence.org

Sincerely,

Bill Wright, Ph.D.
Chief Research Officer
Providence

R. Bryan Bell, MD, DDS, FACS, FRCS(Ed)
Physician Executive
Earle A. Chiles Research Institute
Providence Cancer Institute

Bernard A. Fox, PhD
Scientific Director
Harder Family Chair for Cancer Research
Member and Chief, Laboratory of Molecular and Tumor Immunology
Earle A. Chiles Research Institute
Providence Cancer Institute

James R. Heath Ph.D.,
President
Institute for Systems Biology (a Providence affiliate)

513. International Gene Synthesis Consortium

I am responding: On behalf of an organization

Name: James Diggans

Name of Organization: International Gene Synthesis Consortium

Type of Organization: Professional Organization/Association

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): nucleic acid biosecurity

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: IGSC-comments-to-NIH-Biosafety-RFI-Oct-2026.pdf

Description: The International Gene Synthesis Consortium (IGSC) appreciates the opportunity to provide comments in response to the Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards. The IGSC is the industry association for commercial gene synthesis. Our member companies produce a substantial share of the world's synthetic DNA, and since our founding in 2009, we have developed and voluntarily implemented the Harmonized Screening Protocol to screen every order against a curated database of pathogen sequences, verify customer legitimacy, and keep records to support legitimate investigations. Our comments below are focused on the continued utility of Risk Groups (RGs) as a baseline for risk assessment versus use of Biosafety Levels (BSL), and specifically, how this policy is applied to synthetic biological agents and emerging technologies, especially those that employ artificial intelligence (AI).

October 18 2026

Lyric Jorgenson, PhD

Associate Director for Science Policy

Office of Science Policy
National Institutes of Health
6705 Rockledge Dr. Suite 630
Bethesda, MD 20892

Comments submitted electronically at: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

Re: Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Dr. Jorgenson:

The International Gene Synthesis Consortium (IGSC) appreciates the opportunity to provide comments in response to the Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards. The IGSC is the industry association for commercial gene synthesis. Our member companies produce a substantial share of the world's synthetic DNA, and since our founding in 2009, we have developed and voluntarily implemented the Harmonized Screening Protocol to screen every order against a curated database of pathogen sequences, verify customer legitimacy, and keep records to support legitimate investigations.

Our comments below are focused on the continued utility of Risk Groups (RGs) as a baseline for risk assessment versus use of Biosafety Levels (BSL), and specifically, how this policy is applied to synthetic biological agents and emerging technologies, especially those that employ artificial intelligence (AI). The IGSC believes that RGs should be retained as a baseline for wild-type work but are not sufficient for engineered or multi-source constructs. The IGSC members have a distinct vantage point on risk groups and the strengths and limitations of this approach. Our companies perform a similar risk characterization to ensure our products are used only for peaceful and productive purposes, including scientific research. We have encountered methodological limitations in this process, and this perspective, which we hope is valuable to your efforts, is shared below.

Summary of Recommendations

1. Retain RGs as the baseline for risk assessment of wild-type agents, but do not extend them as the sole basis for assessing engineered, multi-source, or computationally designed constructs.
2. Support the development of a function-based layer of analysis alongside taxonomic classification, which should include areas where sequence-function understanding is weakest.
3. Coordinate with CDC, NIST, the Bureau of Industry and Security, USDA, and international governments and organizations so that function-based criteria developed for biosafety oversight and for nucleic acid synthesis screening remain aligned.
4. Support the establishment of an "Allow List" of sequences and functional elements determined not to contribute to pathogenicity, so that NIH and IBC review capacity is reserved for higher-risk research.
5. Set a defined NIH response timeline for determinations under Section IV-1, with a default pathway allowing IBC approval to proceed if NIH does not respond within that period.

Section V-C: Requirements and Considerations for Risk Assessment for Synthetic Biological Agents or Emerging Technologies

Our experience is that the existing RGs remain a useful baseline for wild-type work and should be retained in that context, but the RG construct breaks down when it comes to the new and emerging synthetic products. The IGSC appreciates the NIH's recognition of the challenges advances in synthetic biology and related technologies pose for ensuring biosafety. We agree that it is becoming easier to develop engineered organisms that are increasingly complex to classify based on risk. Currently, there is not yet an appropriate substitute for the RG construct for this type of agent. As you further consider this topic, we urge you to consider the existing and growing difficulties associated with understanding what 'endows or enhances pathogenicity' and implications for export control of engineered organisms. In particular, we ask that you recognize that risk assessment challenges are not limited to synthetic biological agents containing genetic sequences from multiple sources. AI protein design tools, while enabling remarkable scientific breakthroughs, are introducing new challenges as our scientific community works to understand the risk associated with novel sequences that do not exist in nature.[1]

One reason for these challenges is that our current risk assessment systems define risk at the organism level. This includes Appendix B of NIH Guidelines for Research Involving Recombinant or

[1] https://www.rand.org/pubs/research_reports/RRA4741-2.html

Synthetic Nucleic Acid Molecules[2], which the Agency says it will draw from as it finalizes its new NIH Biosafety Policy for Research Involving Biohazards. Through our work synthesizing and screening nucleic acid sequences, IGSC members have become acutely aware of the limitations of organism-level risk assessments. Nucleic acid synthesis screening approaches are meant to detect sequences associated with pathogenic agents and generally look for sequences that are a 'best match' to controlled, known bacteria, fungi, or viruses.[3] While this approach remains a useful baseline risk assessment strategy, AI-based protein design tools are increasingly challenging the status quo by their ability to create variants of proteins of concern that could evade detection.[4] The nucleic acid synthesis community has developed patches to address these gaps, because currently, to make a functional toxin, models still need significant amounts of known sequence. However, these capabilities are advancing rapidly, and we believe a new non-taxonomic approach is needed for novel biological components and agents.

We applaud the draft policy for anticipating that eventually investigators and Institutional Biosafety Committees (IBCs) will need to conduct a multi-level analysis focused on 1) the RG of the source organism of sequences, 2) the functions those sequences may encode, and 3) the probability of any synergistic effects of the genetic sequences. The first level is tractable; however, existing risk assessment methods cannot address the second and third levels. As such, it is not appropriate to direct IBCs to resolve such questions through deliberation alone. Instead, assessments should use computational methods to predict molecular properties such as structure, binding targets, and functional annotations that may contribute to concerning properties (which themselves await formal definition).

We believe NIH should further support efforts that enable scientists to predict function, including when pathogenic components are in altered contexts. Collaborative public-private conversations are already underway. Specifically, IGSC has funded the Sequence Biosecurity Risk Consortium (SBRC)[5], a community advancing global engineering standards for identifying and managing biological sequences of concern. The work of this body is important for several reasons:

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[2] https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

[3] https://genesynthesisconsortium.org/wp-content/uploads/IGSC-Harmonized-Screening-Protocol-v3.0-1.pdf

[4] Wittmann, B. J., Alexanian, T., Bartling, C., Beal, J., Clore, A., Diggans, J., Flyangolts, K., Gemler, B. T., Mitchell, T., Murphy, S. T., Wheeler, N. E., & Horvitz, E. (2025). Strengthening nucleic acid biosecurity screening against generative protein design tools. Science (New York, N.Y.), 390(6768), 82–87. https://doi.org/10.1126/science.adu8578

[5] https://www.sbrc.bio

- The SBRC has created a set of scientific principles to assess sequence risk for international application. This has, in part, contributed to the construction of a "sequence of concern" dataset by the National Institute of Standards and Technology (NIST).[6]
- SBRC is working to further define sequences of concern based on gene- or domain-level function, i.e., when predicted molecular properties indicate a capacity for biological "functions of concern".

It is important that government policy and guidance align, and for these reasons, we urge NIH to work cooperatively with the biosecurity-focused stakeholders, other United States federal agencies, including the CDC, NIST, the Bureau of Industry and Security, the USDA, as well as international bodies to further develop our collective scientific understanding of how to evaluate potential for harm based on functions inferred from an agent's components.

The shift from a taxonomic approach to risk assessment would also be valuable because it allows us to identify components known to have functions associated with endowing or enhancing pathogenicity, as well as components with benign functions. Understanding what does *not* contribute to an agent's pathogenic activity is equally important to ensure that resources devoted to risk assessment are used efficiently. For example, non-pathogenic nucleic acid sequences found in thousands of bacterial species are factored into a Common Mechanism, a free screening tool that has been developed to easily allow companies to adopt biosecurity protocols that prevent the misuse of synthetic nucleic acids.[7] This approach is in alignment with recommendations from the 2023 Department of Health and Human Services Framework Guidance for Providers and Users of Synthetic Nucleic Acids.[8]

As discussed further below in our comments under Section IV-1, the IGSC is concerned about the burden on NIH and researchers from the potential volume of determinations NIH would have to make under its draft policy, which requires both NIH and IBC approval before a study can begin. This includes "research involving emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the BMBL."

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[6] Laird, T. S., Flyangolts, K., Bartling, C., Gemler, B. T., Beal, J., Mitchell, T., Murphy, S. T., Berlips, J., Foner, L., Doughty, R., Quintana, F., Nute, M., Treangen, T. J., Godbold, G., Ternus, K., Alexanian, T., Wheeler, N., & Forry, S. P. (2025). Inter-tool analysis of a NIST dataset for assessing baseline nucleic acid sequence screening. bioRxiv : the preprint server for biology, 2025.05.30.655379. https://doi.org/10.1101/2025.05.30.655379

[7] Wheeler, N. E., Carter, S. R., Alexanian, T., Isaac, C., Yassif, J., & Millet, P. (2024). Developing a Common Global Baseline for Nucleic Acid Synthesis Screening. Applied biosafety : journal of the American Biological Safety Association, 29(2), 71–78. https://doi.org/10.1089/apb.2023.0034

[8] https://www.aspr.gov/sites/default/files/centers_documents/SynNA-Guidance-2023.pdf

Characterizing what is benign is what makes screening workable at scale; without it, providers would flag sequences that are both ubiquitous and harmless, wasting valuable time and resources. One solution is to allow the federal government to develop an "Allow List" that identifies components and functional elements that do **not** contribute to pathogenicity. Such a list would let NIH clear routine constructs quickly and reserve case-by-case review for genuinely higher-risk research. We recommend that NIH commit in the final policy to developing an Allow List, in coordination with NIST and the nucleic acid synthesis screening community.

NIH should also consider knowledge gaps and where it could contribute to advancing scientific understanding, in part to improve biosecurity assessments. Understanding which sequences contribute to pathogenesis varies across microbial groups, and that unevenness should shape what is achievable today. Bacterial and viral systems are comparatively well characterized, with toxins, secretion systems, and viral immune antagonists often traceable to discrete, experimentally validated sequence elements. The gaps widen for fungi and protozoa, where sequences more often contribute to complex, context-dependent functions such as immune subversion. Fungal virulence, for instance, frequently depends on host immune status and environmental cues and is mediated by traits also required for ordinary growth, so the boundary between a virulence determinant and a housekeeping function may be more difficult to ascertain. Building upon IGSC's previous efforts[9], a significant part of SBRC's work is to define sequences for which their role in pathogenicity is disputed among experts or poorly understood. This can help to focus future research. Targeted investment in these topics would improve both the underlying science and the risk assessments that depend on it.

Section IV-1: Research That Requires NIH and IBC Approval Before Initiation

As noted above, IGSC also has concerns about the proposal in Section IV-1, which routes research involving "emerging, novel, or zoonotic agents for which the RG classification or a recommendation for minimum containment level is not available in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL)" manual to NIH for a case-by-case determination before initiation. IBCs would be barred from approving the work until NIH makes the determination. IGSC members are concerned that a rapidly expanding category of agents – those engineered or created by computational design – may meet the criteria for NIH review under this section but have no entry in the BMBL. The demands of the new policy on NIH, coupled with a potentially dramatic increase in this new category of agents, raise concerns that the subsequent workload will lead to significant

[9] Wheeler NE, Bartling C, Carter SR, et al. Progress and Prospects for a Nucleic Acid Screening Test Set. Applied Biosafety. 2024;29(3):133-141. doi:10.1089/apb.2023.0033

bottlenecks that could have the unintended consequence of delaying the start of important research projects at institutions. We recommend that the final policy establish a defined timeline for NIH determinations under this section — for example, 30 calendar days from submission. NIH may also consider an approach that is specifically inclusive – starting with well-known pathogens and expanding over time as data becomes available clarifying the potential for pathogenicity of individual genetic components not traditionally thought of as posing significant risk.

The IGSC appreciates the opportunity to provide input on updates to the Biosafety Policy for Research Involving Biohazards and remains committed to supporting robust biosafety and biosecurity frameworks. If you would like to discuss our comments further, please contact James Diggans at info@genesynthesisconsortium.org.

Sincerely,



James Diggans, PhD

Chair, International Gene Synthesis Consortium

Vice president, Biosecurity and Policy, Twist Bioscience

514. Jessica Bourquin, PhD, CBSP

I am responding: On behalf of myself

Name: Jessica Bourquin, PhD, CBSP

Name of Organization:

Type of Organization: Academic Institution

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosafety and Biosecurity, Infectious disease research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The NIH Guidelines were originally developed for a different scientific era, and an updated framework is needed to address emerging technologies and biosafety risks that are not adequately captured by the scope of the existing Guidelines. At the same time, NIH has acknowledged that a successful modernization initiative should remove unnecessary oversight of low-risk research. For these reasons, I support NIH's goal of modernizing biosafety oversight and expanding the current framework beyond research involving recombinant or synthetic nucleic acid molecules. While the draft policy expands oversight substantially, several aspects of the proposed scope and associated definitions lack sufficient clarity to ensure consistent implementation and may inadvertently direct limited biosafety expertise toward activities that present little biosafety concern.

The draft defines research involving biohazards as research involving a known or potential risk to human health and certain categories of biological materials. These include wild-type biological agents that cause human disease; genetically modified cells, viruses, or organisms other than plants; toxins, prions, and other self-aggregating proteins; and cells or organisms other than plants containing those materials. While this represents a significant expansion beyond recombinant or synthetic nucleic acid research, the human-health-centered scope and exclusion of plants create potential gaps in biosafety oversight. Human, animal, plant, and environmental health are not mutually exclusive. Under a One Health framework, hazards affecting animals or plants may also have direct or indirect consequences for human health, food systems, ecosystems, or the emergence of disease. The exclusion of plants and the policy's limited treatment of wild-type agents that cause disease only in animals are difficult to reconcile with the stated goal of modernizing oversight for evolving biological risks.

Although other federal agencies provide regulatory oversight for plant and animal health, the NIH Guidelines have historically provided an important institutional framework for local risk assessment, containment determinations, and committee oversight. NIH should reconsider whether these exclusions create gaps in institutional biosafety oversight or leave institutions without a consistent framework for evaluating research involving animal, plant, or environmental health hazards.

Several definitions used to establish the policy's scope also warrant reconsideration. The draft defines a "biological agent" as bacteria, viruses, fungi, or parasites that cause human disease. However, the term

"biological agent" is not universally synonymous with either "pathogen" or "biohazard." In broader scientific usage, a biological agent may simply refer to a biological organism or material, regardless of whether it causes disease. NIH should define "biohazard" according to the capacity of a biological material to cause harm and then distinguish the categories of agents, toxins, prions, and other materials that may meet that definition.

The definition of "biomedical research" is also problematic. The draft defines biomedical research by reference to whether a research topic falls within the mission of NIH. An agency's mission may appropriately determine what research it supports, but it is not a clear scientific or risk-based basis for defining the scope of a federal biosafety policy. Applicability should be determined by the nature and risk of the research rather than whether a particular topic is considered within NIH's mission.

The definitions of "emerging agent or organism" and "novel agent or organism" also require additional clarification. The draft defines an emerging agent or organism as an agent or organism newly identified in nature. In biosafety and public health practice, however, emergence generally refers to a pathogen whose incidence, geographic distribution, or significance is increasing or becoming newly recognized. It does not typically refer to the discovery of a previously unknown organism. Zika virus is a useful example. The virus was known for decades before it emerged as a significant public health concern. What emerged was its significance as a human pathogen, not the organism itself.

The draft's definition of a novel agent or organism raises a related concern. NIH uses the term to describe an agent or organism that does not exist in nature and has been deliberately designed, potentially using components from multiple natural or synthetic sources. However, the terms "novel agent," "novel organism," and "new organism" do not inherently imply deliberate design, pathogenicity, or hazard. Scientists routinely identify previously unknown organisms in nature, and the overwhelming majority have no known adverse consequences for human, animal, or plant health.

The common issue with both definitions is that they place substantial emphasis on whether an organism is new rather than whether it presents a biosafety concern. An organism may be newly discovered without posing a hazard. An organism may be emerging because its significance as a pathogen has become apparent, even though it has been known for decades. Likewise, a deliberately engineered organism may present little or no biosafety concern. NIH should clarify these definitions to ensure institutions focus on identifying hazards rather than determining whether an organism is merely newly identified, newly designed, or otherwise unusual.

Perhaps the most consequential expansion of scope is the inclusion of genetic modifications induced through chemical or radiological means. I understand and support the apparent intent to capture biologically significant changes that may arise through methods other than modern molecular techniques. The concern is not with that intent, but with the breadth of activities the definition may capture.

As written, the definition could bring broad categories of routine chemical mutagenesis, radiological mutagenesis, random mutagenesis, passaging, or selection experiments within IBC oversight even when they do not create a meaningful biosafety concern. Greater clarity is needed regarding which modifications warrant institutional review and which do not.

This concern extends beyond administrative burden. Biosafety professionals and IBC members have limited time and highly specialized expertise. Requiring review of large numbers of low-risk activities can divert attention from hazards that are consequential but not always readily apparent. NIH should provide implementation guidance, including worked examples that clearly distinguish activities requiring IBC registration or review from those that fall outside the intended scope of the policy.

Finally, while I support the inclusion of toxins within the policy's scope, NIH should establish explicit criteria for determining which toxins and uses are subject to the policy. Such criteria should consider toxicity, quantity, concentration, route of exposure, LD50 values, or other scientifically defensible measures of risk. Without clear criteria, institutions are likely to implement the policy inconsistently. Some may adopt highly conservative interpretations that result in registration and review of relatively low-risk materials, while others may reach different conclusions. As with several other areas of the draft policy, clearer boundaries are needed to help institutions reach similar conclusions regarding what research warrants biosafety oversight.

Overall, I support broadening biosafety oversight beyond recombinant and synthetic nucleic acid technologies. However, the scope should more clearly distinguish biological materials from biohazards, newly discovered organisms from emerging pathogens, and genetic modification from changes that alter biosafety risk. Clearer boundaries are needed to prevent inconsistent interpretation and unnecessary review of low-risk activities.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Tiered Oversight and Categories of Review

I generally support NIH's concept of a tiered oversight structure that assigns oversight responsibilities among investigators, institutions, IBCs, and NIH based on risk. However, several aspects of the proposed framework warrant reconsideration to ensure that oversight remains focused on activities that present genuine biosafety concerns and that finite biosafety resources and review capacity are focused on activities that present the greatest uncertainty and potential consequence. The areas of greatest concern involve (1) NIH approval requirements for certain containment determinations and (2) the treatment of activities subject to delegated review.

NIH Approval of Containment Determinations for Emerging, Novel, and Zoonotic Agents

The draft policy requires institutions to petition NIH before research involving certain emerging, novel, or zoonotic agents may proceed when a Risk Group classification or recommended containment level is not available. NIH approval is also required before lowering containment for certain agents and activities. This requirement should be reconsidered. The absence of a specific Risk Group classification or recommended containment level in the BMBL does not necessarily indicate that a biological agent presents unusual uncertainty or warrants mandatory federal review. The BMBL cannot reasonably be expected to provide containment recommendations for every biological agent that may become the subject of research, nor should the absence of a specific recommendation automatically prevent an institution from conducting its own risk assessment.

Institutions routinely evaluate biological agents using established risk assessment principles, available scientific literature, agent characteristics, proposed manipulations, available medical countermeasures, and containment guidance provided in the BMBL. These same approaches can be applied when institutions encounter agents that are not specifically addressed in the BMBL. In many cases, sufficient information exists for an IBC to conduct a thorough risk assessment and establish appropriate containment even when a specific Risk Group classification or BMBL containment recommendation has not been established.

Continued use of Risk Groups would further support this process. Risk Groups provide institutions with a familiar and broadly accepted framework for classifying biological hazards based on their characteristics and potential hazards. When an agent is not specifically classified, institutions can evaluate available information regarding pathogenicity, route of transmission, host range, availability of preventive or therapeutic measures, and other relevant factors to determine an appropriate Risk Group classification.

That classification can then serve as the starting point for determining appropriate containment through the BMBL risk assessment process.

For example, if an agent has been documented to cause disease in humans, has reasonably understood transmission characteristics, and possesses characteristics consistent with a Risk Group 3 pathogen, an experienced IBC should generally be able to conduct a thorough risk assessment and establish containment beginning from a BSL-3 baseline without requiring prior NIH approval simply because the agent lacks a specific BMBL listing.

Containment determinations also depend on local considerations that cannot be fully evaluated at the national level. Geographic location, environmental conditions, competent arthropod vectors, occupational health resources, emergency response capabilities, institutional expertise, and facility characteristics all play a role in risk assessment. An arthropod-borne pathogen may present substantially different considerations for an institution located near the Canadian border than for one located on the Gulf Coast. Local IBCs are often best positioned to evaluate these site-specific factors.

This recommendation should not apply universally. NIH review and approval may be appropriate when research involves agents with substantial uncertainty, unusual pathogenic characteristics, significant biosecurity concerns, or the potential for widespread public health consequences. I also support NIH's proposal to require approval before lowering containment for gene drive-modified organisms, as the ecological and environmental consequences of these technologies remain uncertain.

However, NIH review should be reserved for these higher-concern situations rather than required solely because an agent lacks an established Risk Group classification or recommended containment level in the BMBL. For most agents, institutional risk assessment informed by Risk Groups, established biosafety principles, available scientific literature, the BMBL, and local expertise should remain the primary mechanism for determining appropriate containment.

Delegated Review and Removal of Previously Exempt Activities

My greatest concern with the tiered oversight structure involves the delegated review category.

Under the current NIH Guidelines, certain activities are exempt from IBC review because they have been determined to present sufficiently low risk. Under the draft policy, many of these activities appear to have been moved into the delegated review category. If implemented in this manner, activities that previously required no IBC review could require review by IBC delegates or biosafety staff before they may proceed. This would represent a significant increase in institutional review of activities that have historically been considered sufficiently low risk to warrant exemption.

This change has significant implications for institutional biosafety programs. The issue is not simply administrative burden. Rather, it is the allocation of biosafety resources. Biosafety professionals and IBC members have finite time and specialized knowledge. Requiring review of large numbers of low-risk activities inevitably reduces the time available to identify and evaluate projects that present more significant or less obvious biosafety concerns.

This concern is compounded by the requirement that delegated review approvals be reported to the IBC and documented in meeting records. At many institutions, preparation, review, and approval of IBC meeting minutes already represent a substantial investment of staff time and institutional resources. Requiring large numbers of delegated reviews to be processed, reported, and tracked in a manner similar to higher-risk research is unlikely to improve safety, transparency, or risk assessment outcomes.

If an activity is sufficiently low risk to qualify for delegated review, it should not necessarily require the same level of documentation and reporting associated with full committee review. Otherwise, the distinction between delegated review and full committee review becomes substantially diminished.

NIH should consider retaining appropriate exemptions from the current Guidelines or developing clear exclusions for categories of low-risk research under the new policy. Examples will be particularly important for:

- Genetically modified cells, viruses, and organisms.
- Toxins, prions, and self-aggregating proteins.
- Primary cells and tissues that may contain adventitious agents.
- Other activities that historically fell within exemption categories.

Without clear guidance, institutions will struggle to determine which activities require full IBC review, which qualify for delegated review, and which fall outside the scope of the policy altogether. The result will likely be inconsistent implementation and unnecessary expansion of oversight into activities that present little biosafety risk.

Recommendation

Overall, I support a tiered oversight structure that reserves the most intensive review for the highest-risk research. However, the framework should place greater reliance on institutional biosafety expertise for routine containment determinations and should avoid converting large numbers of historically exempt, low-risk activities into delegated-review activities with extensive documentation requirements.

3. Continued utility of Risk Groups: I strongly support continued use of Risk Groups as part of the biosafety framework. In my view, this should not be framed as a choice between Risk Groups and Biosafety Levels because the two serve different functions.

Risk Groups provide a useful starting point for evaluating the inherent hazards associated with a biological agent. Biosafety Levels are containment recommendations that result from a broader risk assessment process. Risk Groups help characterize the agent, while the BMBL risk assessment framework is used to determine the appropriate containment and risk mitigation measures for the specific research being conducted.

The continued utility of Risk Groups becomes particularly important when agents are genetically modified. Genetic modification does not inherently increase or decrease risk, and the continued utilization of Risk Groups provides a critical baseline for evaluating how a modification changes the hazardous characteristics of an agent and determining the appropriate containment level.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: I support NIH's efforts to improve transparency and establish a more consistent approach to incident reporting. However, several aspects of the incident reporting framework, required reporting thresholds, and public reporting templates warrant reconsideration to ensure that the policy strengthens, rather than discourages, institutional reporting cultures.

Reporting Thresholds and IBC Review

The draft policy appears to substantially expand the number of incidents that must be formally reviewed by an IBC. Under the current NIH Guidelines, reporting requirements focus primarily on significant problems, significant violations, significant research-related accidents or illnesses, and exposures involving recombinant or synthetic nucleic acid research. By contrast, the draft policy requires certain lower-risk incidents to be reported to and reviewed by the IBC, including incidents involving covered research with animals housed at BSL-1/ABSL-1 or BSL-2/ABSL-2 and incidents at those containment levels when first aid is administered but agent-specific treatment is not required.

The policy would benefit from greater clarity regarding the relationship between the incident and the biohazard subject to the policy. As written, it is not always clear whether the incident itself must involve the covered agent or activity, or whether any animal-related event or first-aid event occurring during covered research must undergo formal IBC review.

This distinction is important. A minor injury associated with low-risk research may warrant local review, medical follow-up, and corrective action without necessarily requiring formal IBC review and public reporting. Expanding formal reporting requirements to encompass a large number of low-risk incidents may increase administrative activity without a clear safety benefit.

More importantly, it risks diverting limited biosafety resources away from investigations and corrective actions associated with higher-risk events. Biosafety professionals and IBCs are most effective when their time is directed toward identifying root causes, evaluating meaningful exposures, and preventing significant incidents rather than extensively reviewing events that present little biosafety concern.

Reporting of Potential Laboratory-Acquired Infections

The requirement for immediate reporting of confirmed or potential laboratory-acquired infection also warrants clarification. A confirmed laboratory-acquired infection is a clear reporting threshold. A "potential" laboratory-acquired infection is more challenging because institutions are often unable to determine whether an infection has occurred until an investigation, medical evaluation, and diagnostic testing have been completed.

As written, the requirement may force institutions to speculate about an individual's health status during an active investigation. This may create unnecessary privacy concerns while simultaneously generating reports for events that ultimately prove not to involve an infection at all.

NIH should distinguish a documented or reasonably suspected exposure from a suspected laboratory-acquired infection. Initial notification could be based on an exposure meeting defined criteria, while an LAI determination should follow appropriate medical and epidemiological evaluation.

Public Reporting and the Incident Reporting Template

I do not object to public posting of incident reports, provided the reports contain enough information to explain what occurred, how the institution responded, and what corrective actions were taken without identifying individual researchers.

However, the required incident reporting template should be revised to better protect individual researchers while still preserving transparency. The draft incident reporting template requires inclusion of the principal investigator's name and specifically states that incident reports should not include personally identifiable information other than the PI's name. It further states that names of investigators and information regarding their research may not be redacted solely because they are publicly available elsewhere.

Including the PI's name in publicly posted reports serves little biosafety purpose. The public can understand the nature of the incident, institutional response, corrective actions, and lessons learned without identifying the individual investigator.

This concern is particularly important at institutions conducting animal research, where researchers may already face public scrutiny, harassment, or threats related to their work. Requiring public identification of investigators in incident reports could further discourage reporting and create a perception that the reporting process is punitive rather than corrective.

Institutions with strong reporting cultures often encourage researchers to report even very minor incidents, near misses, and procedural deviations. That culture is critical to effective biosafety oversight. Policies that increase public identification of investigators may unintentionally discourage reporting of

exactly the types of events that provide opportunities for learning and prevention.
NIH should permit publicly posted reports to omit names and other details that would directly or indirectly identify the PI, research personnel, or affected individuals, while retaining the information necessary to understand the incident and institutional response.
Meeting Minutes and Transparency
I support the goal of making institutional biosafety activities more transparent. However, transparency should focus on meaningful biosafety oversight rather than creating reporting requirements that consume substantial institutional resources while providing limited public benefit.
This concern is particularly relevant to both incident review and delegated review activities. If large numbers of low-risk incidents and low-risk protocols are required to be documented in publicly posted meeting minutes at a level of detail comparable to higher-risk activities, institutions will spend increasing amounts of time preparing, reviewing, and approving minutes rather than conducting risk assessments and implementing biosafety improvements.
NIH should consider whether all delegated reviews and lower-risk incident reviews need to be documented in the same manner as full committee deliberations. Meeting minutes should provide transparency regarding the committee's activities, but they should not be structured in a way that effectively eliminates the distinction between delegated review and full committee review.
For delegated approvals and lower-risk incident reviews, the template should permit concise aggregate or summary reporting rather than requiring protocol-level detail comparable to full committee review.
Recommendation
NIH should establish a clearer distinction between incidents that require immediate NIH notification, incidents that require formal IBC review, and incidents that may be managed through institutional biosafety and occupational health processes. The policy should encourage reporting, learning, and corrective action without creating disincentives for investigators to report minor events.
Specifically, NIH should:
• Clarify which lower-risk incidents actually require formal IBC review.
• Refine the reporting threshold for potential laboratory-acquired infections.
• Remove PI names and other identifying information from publicly posted incident reports.
• Ensure that incident reporting templates and meeting minutes focus on the event, institutional response, corrective actions, and lessons learned rather than identifying individual researchers.
• Maintain a reporting structure that encourages robust reporting and continuous improvement rather than one that may discourage reporting of low-risk incidents.
A successful incident reporting system should increase institutional learning and transparency while preserving the reporting culture on which effective biosafety programs depend.

6. Other feedback relevant to this resource: NIH has indicated that it plans to develop implementation resources to support the new policy. While guidance on scope, risk assessment, oversight categories, and incident reporting will be essential, successful implementation will also depend on the institutional authority, qualifications, expertise, and infrastructure necessary to support the expanded responsibilities assigned to IBCs and BSOs.

Implementation Guidance and Worked Examples
The expansion of the policy beyond recombinant and synthetic nucleic acid research will require clear guidance to support consistent implementation. NIH should provide worked examples showing what research is subject to the policy and what research remains outside its scope. Examples are particularly

needed for:
• Genetically modified cells, viruses, and organisms.
• Chemical and radiological mutagenesis.
• Serial passage and selection experiments.
• Emerging and novel agents or organisms.
• Toxins, prions, and self-aggregating proteins.
• Primary cells, tissues, and specimens that may contain adventitious agents.
• Animal studies involving transgenic organisms.
Institutions also need examples distinguishing activities that require full IBC review, delegated review, or no review. This is especially important because activities that were previously exempt from IBC review under the NIH Guidelines appear to fall within delegated review under the proposed framework. Without clear boundaries, institutions will interpret the categories differently and may unnecessarily direct biosafety expertise toward low-risk activities.
Additional guidance should explain how Risk Groups and the BMBL risk assessment framework are intended to work together. NIH should also provide examples showing how institutions should evaluate agents that do not have an established Risk Group classification or a recommended containment level in the BMBL, including when institutional review is sufficient and when NIH consultation or approval is required.
Incident reporting guidance should similarly distinguish among:
• Incidents requiring immediate NIH notification.
• Incidents requiring formal IBC review.
• Incidents that may be addressed through institutional biosafety, occupational health, or laboratory safety processes.
• Near misses and other events suitable for voluntary reporting and institutional learning.
Authority of the IBC and BSO
The draft policy substantially expands the responsibilities of both the IBC and the BSO. Institutions are expected to oversee broader categories of research, perform additional risk assessments, review more incidents, and assume new transparency and reporting responsibilities. However, the draft provides little guidance regarding the authority needed to carry out those responsibilities effectively.
NIH should clarify circumstances in which a BSO may independently intervene to address a significant biosafety concern pending review by the institution or IBC. Guidance should address the BSO's authority to temporarily suspend an activity, restrict an operation, or require immediate corrective action when conditions present a significant risk to personnel, the public, or the environment. This should not be framed as the BSO acting on behalf of the IBC, but as an institutionally designated official exercising defined authority when timely action is necessary.
NIH should also establish clearer expectations for the institutional standing of the BSO, particularly at institutions conducting BSL-3, BSL-4, or gene drive-modified organism research. In these programs, the BSO is not simply an administrative coordinator.
The position serves a critical institutional oversight function and should be afforded authority and independence commensurate with the risks being managed. NIH has already recognized this principle in other oversight frameworks through the role of the attending veterinarian, who is afforded defined authority and institutional standing commensurate with responsibility for animal welfare. A similar approach should be considered for BSOs responsible for overseeing higher-risk biosafety programs.
Qualifications and Competencies

For institutions conducting higher-risk research, NIH should establish expectations for the qualifications and competencies of individuals serving as BSOs. These expectations should recognize the value of advanced scientific education, laboratory research experience, biosafety expertise, professional credentials, continuing education, and demonstrated competency in biosafety risk assessment.

These requirements should be proportional to the risks of the institutional research program. Smaller institutions conducting routine, lower-risk research should not necessarily be subject to the same expectations as institutions operating high-containment laboratories or overseeing gene drive-modified organisms. However, institutions conducting higher-risk research should be expected to appoint BSOs whose training, experience, and authority are commensurate with those responsibilities.

If NIH establishes more formal expectations for BSO qualifications, authority, or institutional structure, implementation should be phased. Institutions will need time to secure resources, recruit qualified personnel, and establish appropriate organizational structures. The existing biosafety workforce may not be sufficient to support immediate nationwide implementation of these expectations.

Conclusion

I support the original intent of NIH's initiative to modernize and strengthen biosafety oversight, but I do not believe the current draft fully achieves that goal. It expands the responsibilities of institutions, IBCs, and BSOs without consistently providing the authority, qualifications, guidance, or institutional infrastructure needed to carry out those responsibilities effectively.

Many of the concerns raised by biosafety professionals are not objections to stronger oversight. They are recommendations for how NIH can achieve stronger oversight more effectively. If NIH seriously considers these recommendations and those offered by others in the biosafety community, the policy could better accomplish its original purpose.

If NIH truly intends to strengthen and promote biosafety, it should be more purposeful in doing so. That means defining not only what institutions must do, but also the authority, professional expertise, resources, and implementation time they will need to do it well.

515. lori smith

I am responding: On behalf of myself

Name: lori smith

Name of Organization:

Type of Organization: Academic Institution

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Recommendations-to-the-National-Institutes-of-Health-Office-of-Science-Policy.pdf

Recommendations to the National Institutes of Health Office of Science Policy

We support the National Institutes of Health (NIH) goal of protecting human health and the environment through effective oversight of research involving biohazards. We ask the Office of Science Policy (OSP) to clarify coverage, establish accountable institutional authority and minimum program support, and align review and reporting with biological risk. These comments consolidate the community's detailed comments and priority requests and follow the draft policy's section order.
The recommendations below concern the Draft NIH Biosafety Policy for Research Involving Biohazards released August 19, 2026, in Notice NOT-OD-26-112. They are proposed revisions, not statements of current requirements. Each topic explains the relevant draft provision before presenting the requested change.

1. Purpose and program identity

Policy reference Section I
The draft describes safe, responsible, and secure research, but its title emphasizes biosafety. Institutional leadership needs a clear statement of the program it must establish and support.
Requests for consideration. Use a consistent title and define whether the required program encompasses both biosafety and biosecurity. State the obligations for each and whether both must be supported to satisfy the policy. Describe the program's full portfolio, including research safety, compliance, responsible conduct and ethical considerations, training, committee review and approval, and security where applicable. A program should not be understood solely as laboratory safety or committee administration.

2. Scope definitions and implementation

Policy reference Section II

Coverage and decision rules

The draft uses broad scope terms and extends obligations beyond directly NIH-funded work. Institutions need consistent rules for deciding which activities and sites are covered.
Requests for consideration. Provide an applicability table and consistent definitions for screening, Assurances, review documents, and reporting forms. Explain how known or potential risk to human health is established, including credible exposure pathways

and the distinction between plausible risk and remote theoretical risk. Clarify biomedical and laboratory research, and work conducted at or sponsored by an institution, including affiliates, leased space, off-site collaborations, teaching, diagnostic, agricultural, and veterinary activities, without treating every biological activity as covered research.

Requests for consideration. Identify activities requiring no submission or review, documentation only, or prior approval. Explain treatment of exclusions and formerly exempt activities. Clarify whether another federal agency's oversight substitutes for any NIH or Institutional Biosafety Committee (IBC) requirement or supplements it, and identify the documentation needed. Provide coverage examples for plant pathogens, routine cell lines, transgenic rodents, and validated inactivated specimens, with evidence supporting each decision.

Implementation period

The proposed effective date would require institutions to identify newly covered work, expand review capacity, train personnel, and update systems while maintaining ongoing research.

Requests for consideration. Allow at least 12 months for full implementation after final guidance and required templates are available. Establish staged milestones for inventory, staffing, training, systems, Biosafety Assurance approval, and conversion of existing submissions. Where appropriate, permit conversion at a significant amendment or scheduled renewal, with safeguards and priority for higher-risk work. Preserve staggered renewal cycles to avoid unnecessary backlogs.

3. Institutional accountability and Biosafety Assurances

Policy reference Section III A

Accountability and minimum program support

The draft requires institutional compliance, training, and program documentation. These obligations need an accountable senior official and explicit minimum resources.

Requests for consideration. Assign overall accountability to the Chief Executive Officer (CEO) or a specifically authorized senior designee. Define the institutional authority needed to direct the program, secure resources, and implement IBC decisions. Require sufficient staffing, office space, administrative systems, records support, communications, training, and occupational health support, proportionate to the volume, complexity, and risk of covered activities.

Requests for consideration. Define minimum support for an IBC office, including professional and administrative capacity for the number of committees or subcommittees and their workload. Explain whether support should be comparable in

function to that provided to Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs). Clarify whether separate program and IBC office leadership is required or whether combined roles are acceptable. State when director, associate director, or other professional staffing is necessary, using functional criteria rather than leaving the minimum undefined.

Requests for consideration. Permit qualified shared personnel and contractors when expertise, authority, availability, reporting lines, and accountability are documented. Require written responsibility or reliance agreements for collaborations, core facilities, vivaria, clinical sites, and externally administered IBCs. Assign review ownership, site evaluations, training, incident response, NIH reporting, and verification of corrective actions. Permit shared evaluations and records while preserving each oversight body's authority.

Assurance submission approval and renewal

A Biosafety Assurance is the institution's documentation of compliance submitted for NIH approval. A predictable process is essential to prevent inconsistent submissions and interruptions during timely renewal.

Requests for consideration. Publish a standardized template distinguishing required, conditional, and optional fields. Include institutional identity and sites; covered activities; authority and reporting lines; IBC establishment and procedures; responsible contacts; compliance and incident procedures; shared arrangements; certifications; signatures; and supporting documents. Keep substantive obligations in the policy rather than adding them through templates.

Requests for consideration. Specify define required institutional signatures, the submission system, and completeness criteria. Identify information that must be public and information that may be provided directly to NIH when public posting is inappropriate or unavailable.

Requests for consideration. Publish OSP review criteria and response targets for receipt, completeness review, consolidated revision requests, and approval, with a contact and escalation process for delays. Approval notices should state scope, effective and expiration dates, conditions, and how the approval term is determined. Set renewal deadlines, advance reminders, and update requirements. Provide written continuity of an existing Assurance during review of a complete, timely renewal, subject to continued compliance and defined limits. Address initial approval separately, and specify when recipients, subrecipients, collaborators, and sites need separate Assurances or may use documented reliance.

Public disclosure and record retention

The draft links Assurances to public program records and requires public minutes and incident reports. Institutions need consistent boundaries between internal records, NIH submissions, and public disclosure.

Requests for consideration. Consolidate disclosure rules and establish allowable redactions for personal, medical, proprietary, and security information. Specify whether posting all incident reports includes minor events and voluntary near misses; consider significant-event summaries and aggregate lower-risk reporting where appropriate. Clarify deadlines when NIH has not issued its final response. Explain retention and public-posting requirements for non-NIH-funded work, records linked to multiple awards, and records subject to longer retention.

4. IBC establishment functions and operations

Policy reference Section III B

Formal establishment and independent authority

The draft requires an IBC but should explicitly define appointment authority, institutional support, delegation, and independent decision-making.

Requests for consideration. Add an establishing-an-IBC subsection with the following proposed language.

The institution shall formally establish an IBC through a written charter or equivalent document. The CEO, or a senior official acting under a specific written delegation from the CEO, shall appoint the Chair and members. The IBC shall have the collective expertise required by this policy. Its charter shall define its charge, authority, appointments, and reporting relationships. Additional institutional duties shall be supported by appropriate expertise and resources.

As an agent of the institution, the IBC shall exercise its assigned oversight authority using independent biosafety judgment, free from inappropriate influence or interference. The institution shall designate an Institutional Official with authority to support the IBC and ensure implementation of its decisions. Institutional officials may impose additional restrictions but shall not override decisions to withhold, suspend, or withdraw approval or authorize covered work without required IBC approval. Members shall be able to raise concerns without retaliation.

Core functions and administrative support

Requests for consideration. Separate substantive oversight functions from committee procedures and administrative tasks. Specify that the IBC shall review the biosafety program, including practices, training, emergency preparedness, and continued compliance; conduct or direct periodic risk-based evaluations of facilities, equipment,

and containment; and report findings, deficiencies, and reasonable corrective plans and schedules to the Institutional Official or designee.
Requests for consideration. Authorize the IBC to review concerns, incidents, unsafe conditions, and noncompliance; require corrective measures and oversee resolution; and recommend improvements to facilities, training, and resources. State that the IBC may approve, require modifications to secure approval, or withhold approval of covered activities and significant changes before implementation. Authorize suspension or withdrawal of approval and cessation of unsafe work under written procedures, with prompt notice to the Institutional Official and defined conditions for resumption.
Requests for consideration. Define evaluation intervals in written institutional procedures proportionate to risk. Permit qualified staff evaluations while retaining IBC responsibility for oversight determinations. Identify immediate stop-work authority and subsequent IBC review. The IBC should approve its minutes and substantive determinations; staff should prepare, retain, redact, and post records, communicate decisions, track deadlines, and prepare authorized submissions. Qualified response teams should be able to investigate and take immediate protective action without waiting for a committee meeting.

Committee procedures and conflicts of interest

The draft mixes meeting rules with functions and allows recused members to count toward voting quorum. A project decision needs sufficient eligible reviewers.
Requests for consideration. Create committee operations subsection specifying quorum, voting thresholds, permitted meeting formats, unaffiliated member participation, required expertise, and conflict disclosure and recusal procedures. Require a quorum of members eligible to deliberate and vote on the affected submission. Explain how to proceed when recusals prevent quorum, and when conflicted members can be present to provide only requested information.

Incident thresholds investigations and reporting

The draft's significant-risk reporting threshold sits alongside broad compliance-violation and equipment-failure categories. Institutions need clear distinctions between NIH notification, internal IBC oversight, and minor events managed under institutional procedures.
Requests for consideration. Provide a reporting decision table. Define confirmed exposure, potential laboratory-acquired infection (LAI), containment loss, minor spill, and near miss. Identify violations reportable regardless of risk and those eligible for internal correction. Explain whether any incident at higher containment includes events without a credible biological exposure or release pathway and distinguish equipment malfunctions with maintained backup containment from compromised containment.

Requests for consideration. Clarify how precautionary medical evaluation, prophylaxis, adventitious agents, and mixed or uncertain exposures affect reportability. Specify initial report recipients, whose awareness starts the 24-hour notification clock, minimum initial information, and treatment of uncertainty. Define the start of the 30-day reporting period and permit an interim report when investigation remains incomplete.
Requests for consideration. Allow coordinated investigations by qualified biosafety, occupational health, clinical, veterinary, and other teams. Specify escalation to the IBC based on risk, recurrence, or unresolved concerns while preserving each body's reporting duties. Provide paired examples of a contained and disinfected spill without exposure versus credible exposure or release; maintained backup containment versus containment failure; and an administrative lapse versus unauthorized work with materially different risks. Identify the facts that change the reporting pathway.

Experienced program leadership and the Biological Safety Officer

The draft requires a Biological Safety Officer (BSO) for certain research and assigns BSO duties to another official when no BSO is designated. Assigning duties alone does not ensure qualified leadership for the expanded program.
Requests for consideration. Require every covered institution to designate an experienced, qualified program lead with demonstrated biosafety expertise and authority proportionate to the research portfolio. Define minimum qualifications, institutional access, reporting relationships, resources, and authority to oversee implementation and escalate unresolved risks. If another official performs BSO duties, require equivalent qualifications for those duties.
Requests for consideration. Clarify the relationship among the program lead, BSO, IBC compliance office director, IBC Chair, and Institutional Official. State whether roles may be combined, how independence is protected, and whether the BSO's IBC role is limited to voting membership or includes program administration. Define functional empowerment comparable to other institutional oversight leaders, including animal welfare directors or institutional veterinarians, and whether a senior administrative appointment is needed. A particular title, such as assistant or associate vice provost or vice president, should not substitute for clearly mandated authority and experience.

5. Investigator responsibilities and voluntary reporting

Policy reference Section III C
The draft assigns investigators safe-research duties that intersect with institutionally managed facilities and services. Its voluntary incident-learning pathway also intersects mandatory reporting and disclosure.
Requests for consideration. Clarify how the Principal Investigator (PI) responsibility for safe research interfaces with institutional responsibility for facility maintenance,

engineering systems, and occupational health services. Responsibility should follow the authority and resources needed to perform the function.

Requests for consideration. Explain how confidential voluntary reporting to the National Biosafety Data and Safety Analysis Center (NBDSAC) interacts with mandatory NIH reporting and public posting. Clearly identify the limits of confidentiality and the voluntary learning pathway so institutions can participate without uncertainty about disclosure obligations.

6. NIH implementation responsibilities and coordination

Policy reference Section III D

The draft assigns NIH interpretation, approval, incident-response, and implementation functions. Institutions need timely, consistent decisions and coordination with related oversight systems.

Requests for consideration. Publish submission checklists, completeness criteria, response targets, and escalation routes for NIH determinations and incident responses, consistent with the Assurance process described above. Publish a crosswalk with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, federal high-risk research requirements, dangerous gain-of-function and potentially dangerous gain-of-function oversight and Select Agent requirements. Identify review ownership, shared information, and effective dates to reduce duplication.

7. NIH review and containment determinations

Policy reference Section IV 1 with related petition provisions in Section III B

The draft reserves certain containment decisions to NIH. Institutions need practical referral criteria that distinguish required federal authorization from local risk assessment.

Requests for consideration. Consolidate overlapping petition provisions. Define when emerging, novel, zoonotic, or unlisted agents require NIH review, with an explicit decision rule when reference information is absent. Explain when published NIH determinations may be reused, where they will be published, and which changes require a new request. Identify limits on local containment decisions and approvals needed before work begins. Clarify interaction with other federal oversight without assuming one approval replaces all others.

8. IBC review pathways and clinical oversight

Policy reference Sections IV 2 and IV 3 with clinical oversight provisions in Section III B

Category boundaries and continuing review

Broad prior-approval categories overlap with lower-risk categories eligible for delegated review. The distinction among committee review, designated member review, administrative processing, and excluded activities needs to be explicit.
Requests for consideration. Provide a review-pathway table and resolve category precedence. Define minor amendments, well-characterized cell lines, low-risk transgenes, potentially contaminated primary cells, and higher-risk manipulations. State whether Section IV 2 requires a convened committee and make delegation under Section IV 3 optional. Clarify eligibility of initial submissions and minor amendments, including amendments to work originally reviewed under Section IV 2. Distinguish administrative changes from changes requiring reassessment and explain the three-year de novo review process and risk-based continuing review between renewals.
Requests for consideration. Provide decisions for routine transfection, established edited cell lines, and personnel or room changes. Assess containment implications before treating a room change as administrative.

Proposed designated member review procedure

Eligible initial submissions and minor amendments may undergo designated member review at IBC's discretion. All members shall receive notice of pending review, access to materials, and a reasonable period specified in written procedures to request full committee review. Any member may request full committee review before approval; a request after approval shall trigger reconsideration under institutional procedures.
If no member requests full committee review during that period, the biosafety administrator, Chair, or institutional designee may assign qualified, unconflicted IBC member reviewers under an IBC-approved procedure. Reviewers may approve, require modifications to secure approval, or refer to the submission to the full committee. Multiple reviewers must agree; unresolved differences shall go to the full committee. Research or an amendment requiring approval shall not begin until approval is granted. Designated member approvals shall be communicated to the IBC when granted and reported in full at its next scheduled meeting for inclusion in the minutes.

Clinical activities and oversight endpoints

Clinical review provisions address administration risks and permit an oversight endpoint at final dosing. Biological risks may continue beyond dosing, and product categories need clearer boundaries.
Requests for consideration. Oversight endpoints should be based on continuing biological risk, including shedding after final dosing. Distinguish manufactured cell products from direct vector administration. Explain what qualifies as higher-risk manipulation, including aerosolization and bladder infusion examples. Define site responsibilities in multicenter studies. Clarify residual institutional biosafety duties for

excluded single-patient expanded access without implying that the exclusion creates an IBC approval requirement.

9. Risk assessment and specialized materials

Policy reference Sections V A through V E

The draft requires risk assessment and mitigation, but institutions need practical methods for assessing modified, nonviable, and unfamiliar materials and documenting acceptable residual risk. Risk Group (RG) describes agent characteristics; Biosafety Level (BSL) and Animal Biosafety Level (ABSL) describe containment - these classifications should not be treated as interchangeable.

Requests for consideration. Explain how controlling policy requirements and reference guidance interact and how differences are resolved. Allow qualified staff to support assessments while investigators retain their responsibilities and the IBC independently evaluates conclusions. Provide a concise format documenting likelihood, severity, exposure pathways, uncertainty, controls, residual risk, and decision authority.

Requests for consideration. Publish examples for attenuated and opportunistic agents; toxin potency, dose, and form; prions and self-aggregating proteins; and validated inactivation. Address short, unknown, proprietary, and artificial intelligence (AI) designed sequences. Explain how encoded function, expected phenotype, and uncertainty affect containment. Distinguish functional gene drives from components, split systems, and intermediates. Clarify influenza strain, segment, and pseudotype combinations and when previous containment determinations remain applicable.

Policy source

Draft NIH Biosafety Policy for Research Involving Biohazards, NIH Notice NOT-OD-26-112, released August 19, 2026. Section references throughout refer to this draft.
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html

516. University of North Carolina at Chapel Hill

I am responding: On behalf of an organization

Name: Chris Broberg

Name of Organization: University of North Carolina at Chapel Hill

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biomedical, infectious diseases, cancer, pharmaceutical development, public health

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposal addresses circumstances in which risks may arise outside the current rsNA-centered framework in that substantial biological risks can arise from wild-type agents, primary specimens, prions, toxins, and other materials that do not necessarily involve recombinant or synthetic nucleic acids. However, the draft's scope raises several questions.

• Primary human materials and clinical specimens. The draft specifically includes primary cells that may contain adventitious agents. NIH should clarify when routine use of human tissues, blood, diagnostic specimens, and established clinical specimen workflows constitutes research requiring IBC approval, as opposed to activities already managed through institutional exposure-control, laboratory safety, and clinical policies.

• Well-characterized cell lines and biological reagents. The draft includes well-characterized cell lines in the delegated-review category, yet the definition of covered biohazards and the conditions for determining that a line presents negligible risk need to be explicit. Otherwise, work that has historically required little or no separate committee attention may generate additional registrations.

• Toxins and self-aggregating proteins. The draft defines toxins as proteins or peptides produced by living organisms that cause harm in humans. NIH should clarify the intended treatment of nonprotein toxins, synthetic or chemically modified biological products, nonpathogenic model systems involving disease-associated proteins, and proteins whose risks are not equivalent to those of infectious agents.

• Research boundaries. Clarify how the policy applies to diagnostic testing, quality-control work, clinical laboratory operations, teaching, core facilities, repository activities, and incidental handling of specimens when those activities intersect with biomedical research.

We support expanding biosafety oversight to encompass biological hazards that may not involve recombinant or synthetic nucleic acids. We recommend that NIH provide more precise scope definitions, including examples of activities that require registration or review and activities that may be managed under existing institutional programs without a separate IBC submission. The policy should clearly distinguish research involving a meaningful biological hazard from routine clinical, diagnostic, educational, and laboratory activities that do not present a comparable risk. NIH should also clarify how

the policy applies to non-NIH-funded work across institutions with funding from non-Federal sources. While we support a broader risk-based biosafety framework, the proposed scope could substantially increase the volume of protocols requiring registration, administrative review, and committee oversight. Without clearer boundaries, institutions may default to submitting a wide range of low-risk activities for IBC review to ensure compliance. This could divert limited committee and biosafety professional resources away from higher-risk research activities and ultimately reduce the effectiveness of oversight. NIH should ensure that expanded scope is accompanied by clear exclusions, exemptions, and risk-based screening mechanisms that prevent unnecessary administrative burden while maintaining appropriate biosafety protections.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): We support risk-tiered oversight and delegation of appropriate reviews. To achieve the stated goal of reducing administrative burden, NIH should define the criteria that distinguish full IBC review from delegated review and administrative screening. Institutions should be permitted to establish documented, risk-based procedures for routine activities and amendments, subject to IBC oversight and escalation when risk changes. The framework should focus committee attention on activities with meaningful biosafety uncertainty or consequence rather than on the number of registrations generated.
We recommend the NIH:
• Establish explicit criteria for full committee review, delegated review, administrative screening, and exemption from separate IBC review.
• Permit documented, institutionally approved risk-triage procedures rather than requiring a separate registration for every covered material or activity.
• Allow the IBC to approve a defined research scope with clearly specified boundaries, so that scientifically equivalent amendments do not repeatedly trigger full review.
• Permit institutional biosafety professionals to perform routine oversight and verify compliance under written IBC-delegated authority.
• Clarify whether and how protocols can be reviewed jointly, or cross-referenced, when they involve the same or equivalent agents, facilities, personnel, and containment controls.
• Explicitly recognize that existing institutional programs, including occupational health, laboratory safety, bloodborne pathogen, clinical laboratory, and animal care programs, may serve as equivalent oversight mechanisms for certain low-risk activities.

3. Continued utility of Risk Groups: Risk Groups and Biosafety Levels should remain complementary components of the framework. RG classifications provide a useful baseline for intrinsic agent risk, while BSL/ABSL determinations must reflect the specific procedures, modifications, exposure routes, biological systems, and containment capabilities involved. NIH should provide consistent decision criteria and timely determinations for novel or uncertain agents, while preserving institutional authority to impose more protective controls based on local risk assessments.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): We support effective compliance mechanisms that reinforce institutional accountability and encourage timely reporting. We recommend a graduated corrective-action framework that distinguishes administrative deficiencies, promptly corrected deviations, and serious or repeated biosafety violations. NIH should harmonize reporting requirements with other applicable federal programs, define reportability thresholds clearly, and establish standardized protections for sensitive information. A de-identified, nonpunitive system for learning from

near-misses would strengthen biosafety culture and improve the quality of incident data.
Compliance requirements should be calibrated to risk and should avoid creating reporting expectations that disproportionately burden institutions while providing limited biosafety benefit. Excessive reporting of low-risk administrative deviations could obscure identification of significant biosafety concerns and discourage timely reporting of minor events and near-misses. Providing processes for variances from NIH policy including providing institutions with a notice of non-compliance, an opportunity to respond to such a notice, and a challenge or appeal process would also drive reporting compliance.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Transparency should make oversight understandable and accountable without making public records a source of additional safety or security risk. The current NIH framework already includes public-facing IBC minutes with content requirements recently updated. Public release of incident reports should serve to inform the public and institutional personnel such that policies and procedures can be improved without risking the release of sensitive personal or research data. Minor and near-miss incidents should generally remain subject to internal institutional review rather than public reporting requirements, thereby encouraging timely reporting and corrective action. Annual aggregate data of reported near misses, or summaries of events, could be reported to allow for learning form made mistakes.
Incident reporting requirements should balance transparency with administrative feasibility. Public reporting requirements that are overly broad, duplicative, or insufficiently risk-based may require significant institutional resources while providing limited additional value for biosafety improvement. Reporting structures should focus on incidents with meaningful biosafety or public health significance, while allowing institutions flexibility to manage minor events and near-misses through internal corrective-action processes.

To facilitate the release of information, we recommend the NIH establishes:
• A uniform definition of the information that must appear in public minutes.
• Explicit rules for redacting protected health information, identifiable employee information, confidential research details, and sensitive security information.
• A standard procedure for institutional review before publication, including who makes the redaction determination and how disagreements are resolved.
• Clear expectations for the treatment of incidents involving multiple protocols, departments, or facilities.
• A practical publication schedule that accounts for incident investigation, institutional review, and required agency coordination.
• Standardized templates that do not inadvertently compel institutions to disclose more sensitive information than necessary.

6. Other feedback relevant to this resource: Successful implementation will require more than publication of a final policy. NIH should provide a detailed policy implementation guide, standardized templates, model procedures, examples for complex research settings, and authoritative guidance for recurring questions. We recommend a phased implementation approach, explicit transition rules for existing approvals, and an evaluation period that allows institutions and NIH to identify unintended burdens or gaps before additional requirements are imposed.
The draft anticipates implementation six months after publication of the final policy. It also contemplates additional guidance on IBC functions, RG classifications, containment, occupational health, and selected

high-risk research categories.
Six months is likely insufficient to inventory newly covered activities, revise policies and electronic systems, train investigators and committee members, and update public-facing reporting procedures. With an appreciation for the extensive nature of the changes proposed, a 12-to-24-month period would allow for a well planned and executed implementation.
NIH should conduct and publish an assessment of the anticipated administrative impact of the revised Guidelines, including estimated increases in protocol registrations, review volume, incident reporting, training requirements, and staffing needs. Many IBCs operate with limited administrative support and biosafety staffing. Expansion of review responsibilities without corresponding flexibility, delegation authority, or additional resources may create challenges for timely protocol review and effective oversight.
Institutions will likely need substantial modifications to electronic research administration systems, protocol management platforms, reporting workflows, and investigator training programs to accommodate newly covered activities and revised review pathways.
The final policy should explicitly allow institutions to implement scalable oversight models based on institutional size, research portfolio, and organizational complexity. A one-size-fits-all approach may be difficult to implement across large academic medical centers, multi-campus systems, and institutions with extensive clinical and translational research programs.

To facilitate a smooth transition to the new Guidelines, we recommend:
1. Standardized risk-assessment, protocol-registration, delegated-review, incident-reporting, and meeting-minutes templates.
2. Examples spanning basic science, translational work, animal research, clinical research, BSL-3 facilities, and Select Agent programs.
3. Clear guidance on the transition of existing approvals, including whether they remain valid until their current expiration or require reassessment.
4. Training materials and model institutional policies, including examples of acceptable delegation and quality assurance.
5. A central source for authoritative interpretations, with defined response targets for requests for containment determinations.
6. A formal opportunity to evaluate implementation problems and revise guidance after institutions have practical experience with the new system.
7. The current biosafety framework should remain valid during and throughout any transitition period until the new framework becomes effective.

Uploaded File: NIH-Draft-Biosafety-Policy-comments-UNC-Chapel-Hill.pdf

The University of North Carolina at Chapel Hill

Request for Comment: Draft NIH Biosafety Policy for Research Involving Biohazards

NOT-OD-26-112

Institution Name: University of North Carolina at Chapel Hill

Point of Contact: Doug Cyr, IBC Chair and Professor of Cell Biology and Physiology

Comments on Draft NIH Biosafety Framework

As an Institutional Biosafety Committee (IBC), we support NIH's effort to modernize the Guidelines and better align oversight with biological risk beyond recombinant and synthetic nucleic acid research. We believe the success of any expanded framework will depend not only on identifying additional biological hazards, but also on ensuring that oversight remains risk-based, scalable, and administratively sustainable. Expanded scope should be accompanied by clear applicability criteria, exemptions where appropriate, delegation authorities, and implementation flexibility so that IBCs can focus limited expertise and resources on activities presenting meaningful biosafety risk.

Question 1: Is the scope appropriate? Are there gaps or overly broad definitions of biohazards?

The proposal addresses circumstances in which risks may arise outside the current rsNA-centered framework in that substantial biological risks can arise from wild-type agents, primary specimens, prions, toxins, and other materials that do not necessarily involve recombinant or synthetic nucleic acids. However, the draft's scope raises several questions.

- **Primary human materials and clinical specimens.** The draft specifically includes primary cells that may contain adventitious agents. NIH should clarify when routine use of human tissues, blood, diagnostic specimens, and established clinical specimen workflows constitutes research requiring IBC approval, as opposed to activities already managed through institutional exposure-control, laboratory safety, and clinical policies.
- **Well-characterized cell lines and biological reagents.** The draft includes well-characterized cell lines in the delegated-review category, yet the definition of covered biohazards and the conditions for determining that a line presents negligible risk need to be explicit. Otherwise, work that has historically required little or no separate committee attention may generate additional registrations.
- **Toxins and self-aggregating proteins.** The draft defines toxins as proteins or peptides produced by living organisms that cause harm in humans. NIH should clarify the intended treatment of

nonprotein toxins, synthetic or chemically modified biological products, nonpathogenic model systems involving disease-associated proteins, and proteins whose risks are not equivalent to those of infectious agents.

- **Research boundaries.** Clarify how the policy applies to diagnostic testing, quality-control work, clinical laboratory operations, teaching, core facilities, repository activities, and incidental handling of specimens when those activities intersect with biomedical research.

We support expanding biosafety oversight to encompass biological hazards that may not involve recombinant or synthetic nucleic acids. We recommend that NIH provide more precise scope definitions, including examples of activities that require registration or review and activities that may be managed under existing institutional programs without a separate IBC submission. The policy should clearly distinguish research involving a meaningful biological hazard from routine clinical, diagnostic, educational, and laboratory activities that do not present a comparable risk. NIH should also clarify how the policy applies to non-NIH-funded work across institutions with funding from non-Federal sources.

While we support a broader risk-based biosafety framework, the proposed scope could substantially increase the volume of protocols requiring registration, administrative review, and committee oversight. Without clearer boundaries, institutions may default to submitting a wide range of low-risk activities for IBC review to ensure compliance. This could divert limited committee and biosafety professional resources away from higher-risk research activities and ultimately reduce the effectiveness of oversight. NIH should ensure that expanded scope is accompanied by clear exclusions, exemptions, and risk-based screening mechanisms that prevent unnecessary administrative burden while maintaining appropriate biosafety protections.

Question 2: Is the proposed tiered oversight structure appropriate and calibrated to risk?

We support risk-tiered oversight and delegation of appropriate reviews. To achieve the stated goal of reducing administrative burden, NIH should define the criteria that distinguish full IBC review from delegated review and administrative screening. Institutions should be permitted to establish documented, risk-based procedures for routine activities and amendments, subject to IBC oversight and escalation when risk changes. The framework should focus committee attention on activities with meaningful biosafety uncertainty or consequence rather than on the number of registrations generated.

We recommend the NIH:

- Establish explicit criteria for full committee review, delegated review, administrative screening, and exemption from separate IBC review.
- Permit documented, institutionally approved risk-triage procedures rather than requiring a separate registration for every covered material or activity.

- Allow the IBC to approve a defined research scope with clearly specified boundaries, so that scientifically equivalent amendments do not repeatedly trigger full review.
- Permit institutional biosafety professionals to perform routine oversight and verify compliance under written IBC-delegated authority.
- Clarify whether and how protocols can be reviewed jointly, or cross-referenced, when they involve the same or equivalent agents, facilities, personnel, and containment controls.
- Explicitly recognize that existing institutional programs, including occupational health, laboratory safety, bloodborne pathogen, clinical laboratory, and animal care programs, may serve as equivalent oversight mechanisms for certain low-risk activities.

Question 3: Should Risk Groups remain the baseline, or should Biosafety Levels become the primary classification?

Risk Groups and Biosafety Levels should remain complementary components of the framework. RG classifications provide a useful baseline for intrinsic agent risk, while BSL/ABSL determinations must reflect the specific procedures, modifications, exposure routes, biological systems, and containment capabilities involved. NIH should provide consistent decision criteria and timely determinations for novel or uncertain agents, while preserving institutional authority to impose more protective controls based on local risk assessments.

Question 4: Are compliance and enforcement mechanisms effective? How should NIH encourage voluntary compliance and address biosecurity?

We support effective compliance mechanisms that reinforce institutional accountability and encourage timely reporting. We recommend a graduated corrective-action framework that distinguishes administrative deficiencies, promptly corrected deviations, and serious or repeated biosafety violations. NIH should harmonize reporting requirements with other applicable federal programs, define reportability thresholds clearly, and establish standardized protections for sensitive information. A de-identified, nonpunitive system for learning from near-misses would strengthen biosafety culture and improve the quality of incident data.

Compliance requirements should be calibrated to risk and should avoid creating reporting expectations that disproportionately burden institutions while providing limited biosafety benefit. Excessive reporting of low-risk administrative deviations could obscure identification of significant biosafety concerns and discourage timely reporting of minor events and near-misses. Providing processes for variances from NIH policy including providing institutions with a notice of non-compliance, an opportunity to respond to such a notice, and a challenge or appeal process would also drive reporting compliance.

Question 5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates.

Transparency should make oversight understandable and accountable without making public records a source of additional safety or security risk. The current NIH framework already includes public-facing IBC minutes with content requirements recently updated. Public release of incident reports should serve to inform the public and institutional personnel such that policies and procedures can be improved without risking the release of sensitive personal or research data. Minor and near-miss incidents should generally remain subject to internal institutional review rather than public reporting requirements, thereby encouraging timely reporting and corrective action. Annual aggregate data of reported near misses, or summaries of events, could be reported to allow for learning form made mistakes.

Incident reporting requirements should balance transparency with administrative feasibility. Public reporting requirements that are overly broad, duplicative, or insufficiently risk-based may require significant institutional resources while providing limited additional value for biosafety improvement. Reporting structures should focus on incidents with meaningful biosafety or public health significance, while allowing institutions flexibility to manage minor events and near-misses through internal corrective-action processes.

To facilitate the release of information, we recommend the NIH establishes:

- A uniform definition of the information that must appear in public minutes.
- Explicit rules for redacting protected health information, identifiable employee information, confidential research details, and sensitive security information.
- A standard procedure for institutional review before publication, including who makes the redaction determination and how disagreements are resolved.
- Clear expectations for the treatment of incidents involving multiple protocols, departments, or facilities.
- A practical publication schedule that accounts for incident investigation, institutional review, and required agency coordination.
- Standardized templates that do not inadvertently compel institutions to disclose more sensitive information than necessary.

Question 6: What implementation resources and additional guidance are needed?

Successful implementation will require more than publication of a final policy. NIH should provide a detailed policy implementation guide, standardized templates, model procedures, examples for complex research settings, and authoritative guidance for recurring questions. We recommend a phased implementation approach, explicit transition rules for existing approvals, and an evaluation period that

allows institutions and NIH to identify unintended burdens or gaps before additional requirements are imposed.

The draft anticipates implementation six months after publication of the final policy. It also contemplates additional guidance on IBC functions, RG classifications, containment, occupational health, and selected high-risk research categories.

Six months is likely insufficient to inventory newly covered activities, revise policies and electronic systems, train investigators and committee members, and update public-facing reporting procedures. With an appreciation for the extensive nature of the changes proposed, a 12-to-24-month period would allow for a well planned and executed implementation.

NIH should conduct and publish an assessment of the anticipated administrative impact of the revised Guidelines, including estimated increases in protocol registrations, review volume, incident reporting, training requirements, and staffing needs. Many IBCs operate with limited administrative support and biosafety staffing. Expansion of review responsibilities without corresponding flexibility, delegation authority, or additional resources may create challenges for timely protocol review and effective oversight.

Institutions will likely need substantial modifications to electronic research administration systems, protocol management platforms, reporting workflows, and investigator training programs to accommodate newly covered activities and revised review pathways.

The final policy should explicitly allow institutions to implement scalable oversight models based on institutional size, research portfolio, and organizational complexity. A one-size-fits-all approach may be difficult to implement across large academic medical centers, multi-campus systems, and institutions with extensive clinical and translational research programs.

To facilitate a smooth transition to the new Guidelines, we recommend:

1. Standardized risk-assessment, protocol-registration, delegated-review, incident-reporting, and meeting-minutes templates.
2. Examples spanning basic science, translational work, animal research, clinical research, BSL-3 facilities, and Select Agent programs.
3. Clear guidance on the transition of existing approvals, including whether they remain valid until their current expiration or require reassessment.
4. Training materials and model institutional policies, including examples of acceptable delegation and quality assurance.

5. A central source for authoritative interpretations, with defined response targets for requests for containment determinations.
6. A formal opportunity to evaluate implementation problems and revise guidance after institutions have practical experience with the new system.
7. The current biosafety framework should remain valid during and throughout any transitition period until the new framework becomes effective.

Conclusion

Overall, we support modernization of the NIH Guidelines and the transition toward a broader biological-risk framework. To be effective, however, the final framework should maintain a clear connection between oversight intensity and actual risk. Expanded scope without corresponding exemptions, delegation mechanisms, and implementation flexibility may substantially increase administrative workload for investigators, biosafety professionals, and IBCs without proportionate biosafety benefit. A successful framework should enable institutions to direct oversight resources toward higher-risk and novel research while allowing routine, well-understood activities to be managed through streamlined processes and existing institutional safety programs.

517. Shannon Ronca

I am responding: On behalf of myself

Name: Shannon Ronca

Name of Organization:

Type of Organization: Academic Institution

Role: Investigator/Researcher

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): infectious disease pathogenesis and epidemiology

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy fails to define all necessary aspects of biohazards and oversight, using vague language throughout. It is an acceptable first draft, but is not an actionable policy.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): It is an acceptable first draft, but is not an actionable policy. The tiered oversight needs to be better defined and currently creates increased administrative burden that may not always be clearly a risk-based oversight policy.

3. Continued utility of Risk Groups: The way it is written, this proposed policy does not seem to create a clear risk-based oversight, but instead generates higher administrative burden.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft incident report and mandate for this to be public is damaging to all involved. Many researchers conduct very specialized studies. Even a report that removes all identifying names would still be easily traced to the research team and could lead to poor outcomes for any involved individuals. For example, if the name of a PI is not allowed to be redacted and you state a graduate student was exposed, someone could easily find the PI's website, learn they only have one graduate student, and harrass that student. That is not a scenario we should allow to occur.

6. Other feedback relevant to this resource: It is an acceptable first draft, but is not an actionable policy in the current format. Terms, requirements, timelines need to be fully defined, the current draft depends on vague language. I have concerns surrounding the vague language particularly as it relates to BSL-3/ABSL-3: "Any incident at BSL-3/ABSL-3" is too vague to be actionable. . There are also concerns around the short timeline for reporting certain things (for example, does the timeline start from the moment of the incident, or the moment the incident is first reported to leadership, or something else?), and for the need to submit incident reports for "Potential releases involving facility and/or equipment failures, even when redundant systems were functioning properly, to address the possibility of risk to personnel and

the community and prevent future occurrences" as this seems to indicate that we'd need to submit incident reports when testing that our redundant systems as part of regular maintenance.

518. Vicente Zuno Fernández

I am responding: On behalf of myself

Name: Vicente Zuno Fernández

Name of Organization: Houston Methodist Research Institute

Type of Organization: Non-Profit Research Organization

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): HMRI is a multidisciplinary biomedical research institution emphasizing the translation of laboratory discoveries into clinical applications.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The expanded scope of the policy is generally appropriate and reflects the need for comprehensive, risk-based biosafety oversight. However, clearer definitions and boundaries are necessary to ensure consistent implementation without imposing unnecessary administrative burdens on low-risk research. In particular, the definition of genetic modification should distinguish permanent genetic alterations from transient nucleic acid expression, such as mRNA-based applications. Replacing the detailed NIH Guidelines with a substantially abbreviated policy, without retaining established exemptions, examples, and interpretative guidance, create uncertainty regarding which activities require oversight and at what level. NIH should clearly distinguish exempt activities, delegated reviews, and full IBC reviews, while establishing consistent, risk-based criteria that prevent oversight gaps without unnecessarily expanding regulatory requirements.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered, risk-based oversight framework is appropriate, provided that responsibilities between federal agencies and local institutions are clearly defined. Local IBCs and BSOs should retain authority to assess and manage routine research activities based on institution-specific risks, while federal oversight should focus on higher-risk research, significant incidents, and activities requiring specialized review. The policy should establish clear criteria for escalating oversight, preserve institutional flexibility, and avoid duplicative administrative requirements. Additionally, federal expectations should be proportional to the actual biological risks involved rather than imposing uniform requirements across all research activities.

3. Continued utility of Risk Groups: Risk Groups (RGs) remain valuable as a baseline for biological risk assessment and should be retained within the proposed policy. However, RG classifications alone are insufficient to determine appropriate containment, particularly when organisms undergo genetic modifications that may alter pathogenicity, transmissibility, host range, or other biological characteristics. Biosafety Levels (BSLs), as described in the BMBL, provide a more comprehensive, activity-based framework that considers agent characteristics, experimental procedures, exposure potential, and available safeguards. NIH should preserve the distinction between RG classifications and

BSL containment requirements while emphasizing comprehensive, risk-based assessments conducted at the institutional level. This approach would provide flexibility without compromising biosafety or introducing unnecessary regulatory complexity.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary compliance by providing accessible guidance, standardized risk assessment tools, training resources, and model institutional policies. Voluntary adoption should remain flexible and risk-based, particularly for smaller institutions with limited biosafety resources. Clear distinctions between mandatory requirements and recommended practices would promote broader participation without creating unnecessary administrative or financial burdens.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The proposed templates may improve consistency and transparency but should remain flexible and proportional to risk. Incident reporting should clearly distinguish events requiring immediate notification from those appropriate for routine institutional documentation. Reporting requirements should avoid duplicating information already captured through institutional incident management systems. Similarly, IBC meeting minutes should document substantive discussions and decisions without imposing excessive administrative burdens. Public disclosure requirements should adequately protect confidential research information, personnel privacy, and institutional security.

6. Other feedback relevant to this resource: NIH should provide comprehensive implementation guidance, including standardized risk assessment tools, clearer definitions, practical examples, and decision-making frameworks for determining oversight requirements. Additional guidance is particularly needed regarding BSO qualifications and responsibilities, IBC review thresholds, incident reporting criteria, and the distinction between mandatory requirements and recommended practices. Retaining relevant examples and interpretations from the existing NIH Guidelines would promote consistency and reduce uncertainty. NIH should also provide adequate transition periods, training resources, and technical assistance to support implementation without imposing unnecessary administrative burdens.

Uploaded File: Comments-for-Submission-Draft-NIH-Biosafety-Policy-10.7.2026-1.pdf

Description: Vicente Zuno - Comments for Submission - Draft NIH Biosafety Policy

October 7, 2026

Dear NIH OSP,

I appreciate the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards. I submit these comments in my individual capacity as a biosafety professional with experience supporting IBC oversight, conducting biological risk assessments, investigating laboratory incidents, inspecting containment laboratories, and advising investigators.

I support NIH's effort to modernize biosafety oversight, expand the framework beyond recombinant and synthetic nucleic acid research, and establish a more risk-based system. However, several areas would benefit from clarification or additional guidance:

1. Qualifications and Competency Requirements for Biological Safety Officers

I strongly recommend that NIH establish minimum competency expectations for Biological Safety Officers (BSOs).

The draft assigns BSOs significant technical responsibilities, including inspection of containment facilities and equipment, assessment of compliance, investigation of incidents, identification of violations, and technical advice to investigators and the IBC. These functions require specialized knowledge and professional judgment, yet the draft specifies no minimum education, training, experience, or competency requirements.

NIH should establish a competency-based framework addressing areas such as biological risk assessment, containment, laboratory practices, incident investigation, applicable standards, and IBC oversight. Institutions could retain flexibility in demonstrating competency through education, experience, training, professional credentials, or a combination thereof.

2. Assignment of BSO Responsibilities to an "Other Official"

I am particularly concerned by the provision stating that, if an institution does not designate a BSO, another official must assume the BSO's responsibilities.

These responsibilities remain technical regardless of the title of the individual performing them. Incident investigation, containment assessment, laboratory inspection, and technical recommendations to an IBC require appropriate expertise.

NIH should remove this provision or clarify that any individual performing BSO functions must meet equivalent competency expectations. Otherwise, the Policy risks creating significant variability in the qualifications of those responsible for institutional biosafety oversight.

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

3. Circumstances Requiring Appointment of a BSO

NIH should reconsider limiting mandatory BSO appointment primarily to institutions conducting BSL-3/BSL-4 research or research involving GDMOs.

The proposed Policy expands biosafety oversight to wild-type biological agents, toxins, primary cells, and other biohazards. An institution could maintain a substantial BSL-2 program involving human pathogens while having significant responsibilities under the Policy without being required to designate a BSO.

NIH should either broaden the circumstances requiring a qualified BSO or provide criteria based on the size, complexity, and risk profile of an institution's research program.

4. Qualifications and Procedures for Delegated IBC Review

I support delegated review for appropriate lower-risk research, but additional guidance is needed regarding who may perform these reviews and under what conditions.

NIH should clarify whether delegated reviewers must be voting IBC members, whether a BSO may independently conduct delegated review, minimum reviewer competency, conflict-of-interest requirements, documentation expectations, and circumstances requiring elevation to full committee review.

A model delegated-review procedure would improve consistency among institutions while preserving institutional discretion to apply more restrictive review standards.

5. Activities Outside the Policy and Removal of Existing Exemptions

The draft identifies certain activities as outside the Policy but does not provide an exemption structure comparable to the current NIH Guidelines.

Clear boundaries are essential to prevent unnecessary administrative burden and inconsistent interpretation. NIH should develop a decision framework distinguishing:

- Activities outside the Policy;
- Activities not requiring IBC review;
- Activities eligible for delegated review;
- Activities requiring full IBC review; and
- Activities requiring both NIH and IBC review.

Representative examples of commonly conducted biomedical research would be particularly useful.

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6. Incident-Reporting Thresholds and Public Posting

Additional guidance is needed to distinguish incidents requiring NIH reporting from those that may be managed institutionally.

Terms such as “minor spill,” “low-risk agent,” “breach of containment,” and “significant risk to human health” may be interpreted differently among institutions. NIH should provide a decision tree and representative examples identifying events requiring immediate NIH reporting, routine reporting, internal review only, or no formal reporting.

NIH should also establish clear standards for redacting publicly posted incident reports to protect personal and medical information, confidential research information, security-sensitive facility information, and ongoing investigations.

7. Relationship Between Risk Groups and Biosafety Levels

I encourage NIH to retain Risk Groups as one component of biological risk assessment while providing clearer guidance regarding their appropriate use.

Risk Group and Biosafety Level are not interchangeable. Risk Group describes characteristics of a biological agent, whereas containment level should result from a protocol-specific risk assessment considering the agent, procedures, concentration, volume, exposure routes, aerosol generation, animal models, genetic modifications, and other experimental factors.

Because confusion between RG classification and BSL assignment remains common, the new Policy provides an opportunity to clearly distinguish these concepts and reinforce protocol-specific risk assessment.

8. Implementation Guidance and Transition Period

The proposed Policy represents a substantial change in institutional biosafety oversight. Institutions may need to revise committee jurisdiction, procedures, electronic systems, delegated-review processes, incident-reporting procedures, institutional websites, training, and existing research registrations.

NIH should make implementation resources available well before the effective date. Particularly useful resources would include:

- A model Institutional Biosafety Assurance;
- A model IBC charter;
- A biosafety registration template;
- A delegated-review procedure;

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- Scope and review-category decision trees;
- Incident-reporting guidance;
- BSO competency guidance;
- IBC and reviewer training materials;
- Public disclosure and redaction guidance; and
- Transition guidance for existing research.

These resources would be especially valuable to smaller institutions without dedicated biosafety or regulatory personnel.

9. Definition of Genetic Modification

I recommend that NIH revise or clarify the proposed definition of "genetic modification."

The draft includes introduction of nucleic acid molecules that "can be transcribed or translated." Transcription or translation alone, however, does not necessarily result in a stable or heritable genetic alteration.

For example, transient introduction of mRNA can result in translation of an encoded protein without altering the cellular genome. Likewise, non-integrating nucleic acid constructs may produce transient expression without creating a stable genetic modification.

NIH should clarify whether transient nucleic acid expression is intentionally being classified as "genetic modification." If such research is intended to remain within the Policy, terminology should distinguish transient nucleic acid expression from stable genomic modification. If not, the definition should be revised accordingly.

Clear terminology is essential because this definition directly affects whether research falls within the Policy and what oversight is required.

10. Clarity and Proportionality in Compliance and Enforcement

The proposed Policy includes potentially significant consequences for noncompliance, including additional terms and conditions, termination, and effects on future NIH funding decisions. Given the breadth of the Policy and its transition from detailed Guidelines to a more streamlined framework, NIH should clearly explain how compliance and enforcement determinations will be made.

NIH should clarify:

- How inadvertent or good-faith interpretive errors will be distinguished from serious, repeated, reckless, or intentional noncompliance;

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

- Whether institutions will ordinarily have an opportunity to implement corrective actions before severe enforcement measures;
- What factors will determine the severity of an enforcement response;
- How actual or potential biosafety risk will influence enforcement; and
- How NIH will address provisions reasonably subject to more than one interpretation.

A risk-based biosafety policy should be accompanied by a risk-based and proportionate compliance framework. Clear enforcement principles would encourage self-identification and correction of problems while reducing the risk of disproportionate consequences for ambiguous or low-risk compliance issues.

Conclusion

The proposed NIH Biosafety Policy is an important opportunity to modernize biological research oversight, but its success will depend on clear scientific terminology, qualified biosafety professionals, and sufficiently detailed implementation and enforcement guidance.

As NIH expands institutional responsibilities, it should establish appropriate competency expectations for BSOs and others performing BSO functions. Key definitions, including "genetic modification," should also be scientifically precise and avoid unintentionally capturing activities that do not constitute stable genetic alteration.

Finally, simplification of the current NIH Guidelines should not eliminate the examples and distinctions institutions need to understand their obligations. Where noncompliance may carry significant funding consequences, institutions should be able to determine prospectively what the Policy requires. A risk-based biosafety policy should therefore be supported by clear implementation guidance and a proportionate, risk-based compliance framework.

Thank you for considering these comments.



Vicente Zuno, RBP (ABSA), CPH (NBPHE) – Provisional

Disclaimer: This submission reflects my personal views and professional experience and does not represent the official position or policies of my employer or any affiliated institution.

519. Andrea Vogel

I am responding: On behalf of myself

Name: Andrea Vogel

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosafety

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: See attached

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): See attached

3. Continued utility of Risk Groups: See attached

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): See attached

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: See attached

6. Other feedback relevant to this resource: See attached

Description: A PDF of comments to the NIH about the draft NIH Biosafety Policy for Research Involving Biohazards

520. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Non-Profit Research Organization

Role: Other

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed scope would benefit from greater precision to support consistent application across varied institutional settings. The final policy should define “research” and “biohazard” clearly and distinguish covered research from clinical diagnostics, public-health testing, assay verification and validation, routine analytical testing, product-support testing, and other activities that use biological materials without seeking generalizable knowledge. Terms such as “potential,” “acceptable,” and “significant risk” should be accompanied by objective criteria, a decision tree, and representative examples for academic, contract-research, analytical, and public-health settings.

Institutions also should be able to rely on reasonable, documented classification decisions made in good faith under then-current NIH criteria and examples (eg the NIH Guidelines Appendices A and B), unless the decision was based on a material omission or is affected by new information or a material change in the work.

NIH should clarify the organizational boundaries of a covered institution, the meaning of research “sponsored by” an institution, and the treatment of affiliates, subsidiaries, separately incorporated locations, subrecipients, subcontractors, and client-sponsored activities. Potential oversight gaps involving recombinant plant and plant-pathogen research should be addressed through risk-based criteria developed in coordination with USDA or another appropriate federal agency.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered system is appropriate if federal oversight establishes clear minimum requirements while preserving local authority to apply project-specific judgment. Federal review or mandatory standards should focus on activities involving substantial hazards, novel agents, high uncertainty, or national-security implications. Institutions should be able to use documented administrative or delegated review for well-characterized, low-risk activities and reserve full IBC review for work whose hazards, uncertainty, or proposed controls warrant committee deliberation.

The final policy should identify the federal authority responsible for administering an expedited process

for emerging, novel, or zoonotic agents when no current risk-group recommendation exists. That process should include interim containment recommendations, defined submission requirements, points of contact, decision timelines, and time-limited emergency determinations so that appropriately qualified laboratories can perform urgent diagnostic, assay-development, and countermeasure work under defined minimum controls.

NIH should specify which project-review requirements are satisfied by equivalent federal oversight and which institution-level obligations—such as assurance, reporting, training, recordkeeping, and public posting—remain applicable.

3. Continued utility of Risk Groups: Risk Groups remain a useful baseline for understanding the intrinsic hazards of agents and should be preserved in an authoritative, publicly accessible federal resource. They should not, however, be treated as a stand-alone containment determination, particularly when an agent is genetically modified. Institutional risk assessment should consider whether a modification may alter host range, pathogenicity, transmissibility, environmental stability, treatment susceptibility, toxin production, or other relevant characteristics, and should select practices, equipment, and facility controls using the BMBL.

NIH has stated that implementation resources will draw from current Risk Group classifications and other existing guidance. The final policy should expressly preserve those resources (eg NIH Guidelines Appendix B) until authoritative replacements are published, clarify the relationship between RG and BSL, maintain a searchable record of generally applicable determinations for previously reviewed experiment types, and confirm that existing approvals remain valid unless new information or a material change warrants reassessment.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Voluntary compliance is most likely when NIH offers practical tools and clear incentives rather than extending mandatory requirements indirectly. Useful resources would include modular model policies, decision tools, training materials, sample risk assessments, and adaptable templates that institutions may adopt without becoming subject to unrelated funding requirements.

A tiered recognition or self-attestation program, confidential technical assistance, and access to the centralized incident-learning system would further encourage participation. NIH also should make clear how voluntary adoption affects an institution's legal and programmatic obligations, including that use of NIH tools or templates does not by itself create additional public-disclosure duties or implied certifications beyond the practices expressly adopted.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Appropriate reporting and accountability for significant biosafety incidents and compliance failures is critical to promoting transparency and trust. The templates should identify minimum data elements while allowing institutions to use equivalent records and systems. The incident-learning function should encourage timely reporting, root-cause analysis, corrective action, and sector-wide learning, while preserving appropriate enforcement for willful misconduct, material nondisclosure, or repeated noncompliance.

The proposed National Biosafety Data and Safety Analysis Center could advance those objectives by

aggregating, de-identifying, and analyzing incident and near-miss data. NIH should use that centralized mechanism as the principal vehicle for public learning. Institutional reporting should support transparency, accountability, and corrective action, while institution-level public posting should be limited to information that can be disclosed without compromising privacy, security, legal obligations, proprietary information, or client confidentiality.

Although the draft contemplates allowable redactions, NIH should establish objective withholding and redaction standards so transparency obligations are applied consistently and do not inadvertently create safety, security, privacy, or legal risks. Institutions should not be required to publish information that could identify personnel or facilities, compromise physical security, cybersecurity, personnel safety, or appropriate access controls, disclose restricted or classified information, conflict with applicable legal or sponsor restrictions, interfere with an investigation, or expose proprietary research information. Public outputs should focus on aggregate trends, lessons learned, contributing factors, corrective actions, and other information that advances public understanding without increasing operational or security risk.

The meeting-minutes template should document attendance, quorum, recusals, risk determinations, required controls, votes, and action items without requiring sensitive protocol details to be reproduced in public-facing records. It should allow restricted information to be reviewed by an authorized subset or designated official and referenced in non-sensitive minutes. NIH should also clarify how public-posting requirements interact with the Federal Select Agent Program, classified and controlled information requirements, privacy obligations, contractual restrictions, law-enforcement activities, and other applicable federal requirements.

6. Other feedback relevant to this resource: Additional implementation resources will be important to the clarity, consistency, and scalability of the future national framework. NIH should provide a scope decision tree; examples distinguishing research from diagnostics, validation, analytical, and product-support activities; extend the institutional requirement for biosafety officers to BSL-2 laboratories; establish baseline competence requirements for biosafety officers, individuals designated by the institution to fulfill the responsibilities of a biosafety officer, and individuals delegated to review and approve low-risk research; risk-tiering and delegated-review criteria; an expedited pathway for emerging agents; and a maintained resource for RG assignments and generally applicable determinations for previously reviewed experiments.

Guidance is also needed on institutional applicability, organizational boundaries, subawards and subcontracts, client-funded work, amendment thresholds, grandfathering, de novo renewals, review timelines, training documentation, institutional registration, PI and biosafety-official responsibilities, multi-site programs, and the relationship to Select Agent, USDA, biosecurity, classified, and other access-control requirements. The final policy should allow equivalent institutional systems and documentation when they satisfy the substantive requirements.

The draft proposes an effective date six months after publication of the final policy. NIH should consider whether that period is sufficient for institutions with large portfolios, multiple sites, or high volumes of short-duration projects, and whether a longer or phased implementation period with prioritized milestones would better support orderly implementation. Existing approvals should remain valid during transition unless new information or a material change warrants reassessment.

521. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Since Risk Group assignments are not provided in the BMBL, my recommendation is to only require assigning biosafety levels rather than assigning both risk groups and biosafety levels. If risk group assignment is required, I recommend retaining and expanding Appendix B and providing a definitive source or clear criteria for assigning Risk Groups. Without standardized Risk Group classifications, institutions may reach different conclusions for the same agent, reducing consistency across the research community.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The policy requires institutions to post incident reports on their website using the NIH template that includes the PI's name. I believe this may discourage incident reporting and, in a small laboratory with few researchers, potentially identify the affected individual with the amount of detail required in the template. I recommend that the requirement for the name of the PI name and grant numbers be removed from the posted incident report.

6. Other feedback relevant to this resource: It's not clear if my attachment uploaded. Therefore, I'm providing all of my comments in this section to ensure you receive them.

1. Posting incident reports with PI's name on institutions' website
The policy requires institutions to post incident reports on their website using the NIH template that includes the PI's name. I believe this may discourage incident reporting and, in a small laboratory with few researchers, potentially identify the affected individual with the amount of detail required in the template. I recommend that the requirement for the name of the PI name and grant numbers be removed from the posted incident report.

2. Three-year de novo review
The draft policy indicates IBC approval may not exceed three years, after which the investigator must submit a de novo registration for review. I believe a 5-year de novo review is more appropriate to coincide with the typical five year funding cycle. Requiring a PI to annually renew their IBC registration will ensure PIs are continually reminded that an amendment must be submitted for additional planned work not covered under the original registration. In addition, a provision for extending work past the 5-year expiration at the discretion of a delegated member or biosafety officer, would allow accommodation for extenuating circumstances. If the three year de novo requirement remains, then registrations currently approved for five years should be grandfathered in to allow renewal at the end of their current cycle. Doing otherwise, would create an enormous administrative burden and potentially rushed reviews of de novo registrations.

3. Exemptions of very low-risk research
The proposed draft does not include a list of exemptions for very low-risk research. I recommend retaining the current list of exemptions in the NIH Guidelines and adding further exemptions for the following:
• Well characterized tissue-culture cells genetically modified with recombinant or synthetic nucleic acid molecules, provided that the modification does not introduce or produce an infectious biological agent, biological toxin, gene-drive system, or other biological hazard covered by the policy.
• Caenorhabditis elegans and Drosophila melanogaster when the modification does not introduce a biohazard, such as, a biological agent, toxin, gene-drive system, increased pathogenicity, or increased transmissibility.
• Escherichia coli BL21

4. Toxins
I recommend retaining the current NIH Guidelines threshold of a human LD50 of less than 100 nanograms per kilogram body weight and excluding plant-derived toxins that are not on the select agent list. Toxins behave like chemicals and typically fall under the purview of chemical safety programs (with the exception of select agent toxins).

5. Review of primary cells
I recommend that recombinant and wild type primary cells are permitted delegated since these materials may contain RG2 agents which are permitted delegated review. If the primary cells are suspected of containing an RG3 or RG4 agent, then full committee review would be appropriate.

6. Clarifications
Please clarify the following:
a. Exemption of CAR T-cells from clinical research coverage due to their low risk
b. That the very rare occurrence of opportunistic or nosocomial disease does not necessarily bring an otherwise RG1 wild-type agent within the scope of the policy.
c. Whether HIV, hepatitis viruses, and other bloodborne pathogens potentially present in primary materials are considered adventitious agents

d. Whether mRNA, microRNA, miRNA mimics etc. in animals are permitted delegated review
e. Whether RG2 agents only expressing reporter genes are permitted delegated review

Description: Comments

522. The University of Sydney

I am responding: On behalf of an organization

Name: Lan Le

Name of Organization: The University of Sydney

Type of Organization: Academic Institution

Role: Other

Role - Other: Biosafety

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Section II applies the Policy to non-NIH-funded research at any institution receiving any NIH funding, and the Compliance and Enforcement provisions require institutions, as a term and condition of NIH funding, to ensure that all research conducted at or sponsored by them complies, whatever the funder. This is a significant change for institutions outside the United States. Under the current NIH Guidelines, the institution-wide requirement applies to research within the U.S. and its territories (Section I-C-1-a), while research performed abroad is covered only where it is supported by NIH funds or involves human testing of NIH-developed materials (Section I-C-1-b), and must comply with host-country rules where they exist (Section I-C-1-b-(3)).The University recognises that the Policy provides a sound framework of fundamental biosafety principles and practices for biomedical research, particularly as a model for institutions outside existing regulatory frameworks. However, it is not clear whether the Policy applies to foreign institutions that collaborate with a U.S. institution receiving NIH funding, or that receive NIH funding and conduct the research outside the U.S. The Draft also does not define “sponsored by” or “at the institution” or say whether an institution that receives NIH funds only as a subaward “receives any NIH funding”. As currently drafted, the Policy would cover an institution’s entire research portfolio, not just the NIH-funded work.

For a large Australian university such as ours, this means a single NIH award could bring work funded by our National Health and Medical Research Council, the Australian Research Council, the Medical Research Future Fund and industry under NIH terms. It could also reach facilities shared with affiliated hospitals and research institutes that the university cannot contractually bind.

Recommendation: We ask NIH to limit mandatory scope to only NIH-supported projects and the laboratories where they are conducted, to define "sponsored by" and "at the institution" (including affiliates, adjuncts and shared facilities), to clarify whether subaward-only funding brings an institution within scope, and to leave wider adoption to the voluntary provisions.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The University supports the Policy's principle of tiered oversight calibrated to risk. The main gap for an Australian institution is that the Policy does not recognise foreign regulatory systems. The import, export, use, storage and transport of biological materials in Australia are already governed by Federal and State legislation, regulatory schemes, and technical standards. These protect Australian public health and safety, prevent the introduction and spread of infectious diseases and pests, safeguard the environment and give effect to Australia's international treaty obligations. Non-compliance carries serious consequences including suspension of research, loss of licences and permits, and criminal penalties. Most of the Policy's scope therefore already has a regulated counterpart in Australia, as the table below shows. Requiring foreign institutions to meet both systems would duplicate processes for the same work without improving safety and runs against the Draft's stated aim of reducing red tape.

The current NIH Guidelines already recognises this. Section I-C-1-b(3) provides that, for NIH-supported research performed abroad, if the host country has established rules for the conduct of recombinant or synthetic nucleic acid research, the research must comply with those rules; only where the host country has no such rules must the research be reviewed by an NIH-approved Institutional Biosafety Committee or equivalent body and accepted by the host country's national authority. The Draft Policy contains no equivalent provision. Australia's Gene Technology Act 2000 already requires accredited organisations to operate Institutional Biosafety Committee under the Regulator's guidelines, so the oversight structure NIH seeks already exists in Australian law.

As currently drafted, research that falls under the "purview of another federal agency" may proceed under that agency's oversight, but this appears limited to U.S. agencies. We ask NIH to extend this recognition to foreign institutions operating within mature, nationally regulatory frameworks, such as Australia's, where equivalent oversight mechanisms already exist.

Recommendation: We ask NIH to retain the host-country deference in Section I-C-1-b(3) of the current NIH Guidelines and to establish an equivalency or foreign assurance pathway, under which institutions may certify compliance with their national biosafety law while committing to the Policy's core principles, including risk assessment before work begins, proportionate biosafety oversight using a tiered review approach, and appropriate containment and approval requirements.

3. Continued utility of Risk Groups: The University supports the Policy's principle of tiered oversight calibrated to risk. The main gap for an Australian institution is that the Policy does not recognise foreign regulatory systems. The import, export, use, storage and transport of biological materials in Australia are already governed by Federal and State legislation, regulatory schemes, and technical standards. These protect Australian public health and safety, prevent the introduction and spread of infectious diseases and pests, safeguard the environment and give effect to Australia's international treaty obligations. Non-compliance carries serious consequences including suspension of research, loss of licences and permits, and criminal penalties. Most of the Policy's scope therefore already has a regulated counterpart in Australia, as the table below shows. Requiring foreign institutions to meet both systems would duplicate processes for the same work without improving safety and runs against the Draft's stated aim of reducing red tape.

The current NIH Guidelines already recognises this. Section I-C-1-b(3) provides that, for NIH-supported

research performed abroad, if the host country has established rules for the conduct of recombinant or synthetic nucleic acid research, the research must comply with those rules; only where the host country has no such rules must the research be reviewed by an NIH-approved Institutional Biosafety Committee or equivalent body and accepted by the host country's national authority. The Draft Policy contains no equivalent provision. Australia's Gene Technology Act 2000 already requires accredited organisations to operate Institutional Biosafety Committee under the Regulator's guidelines, so the oversight structure NIH seeks already exists in Australian law.

As currently drafted, research that falls under the "purview of another federal agency" may proceed under that agency's oversight, but this appears limited to U.S. agencies. We ask NIH to extend this recognition to foreign institutions operating within mature, nationally regulatory frameworks, such as Australia's, where equivalent oversight mechanisms already exist.

Recommendation: We ask NIH to retain the host-country deference in Section I-C-1-b(3) of the current NIH Guidelines and to establish an equivalency or foreign assurance pathway, under which institutions may certify compliance with their national biosafety law while committing to the Policy's core principles, including risk assessment before work begins, proportionate biosafety oversight using a tiered review approach, and appropriate containment and approval requirements.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): The University of Sydney welcomes the Policy's intention to serve as a model framework. However, a mandatory institution-wide requirement may discourage voluntary uptake and make international collaborations harder to sustain. Voluntary adoption is more likely if NIH offers a path that accommodates existing national regimes. We suggest:

- A verification of alignment with the Policy's principles, available to institutions that already operate under an accredited national biosafety regime, in place of full Assurance;

- A published self-assessment tool and mapping to international standards (the WHO Laboratory Biosafety Manual, 4th edition, and ISO 35001), so institutions can show equivalence;

- Open access to implementation of resources, training materials and templates for institutions not subject to the Policy, adaptable to local law.

The University value the partnership with the NIH and welcome the opportunity to engage further with NIH's Office of Science Policy as the Biosafety Policy is developed.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: While the University supports transparency and prompt incident reporting, we have concerns about the requirements for an Australian institution.

Application beyond NIH-funded research is unclear: Section II extends the Policy to non-NIH-funded research at any institution that receives NIH funding, but the posting and reporting requirements do not

say whether they follow. It is unclear whether minutes and incident reports covering non-NIH-funded work must be posted or notified to NIH, or whether the requirements apply only to NIH-supported research.

Duplication of established incident reporting systems: Institutions in Australia already operate established systems for reporting, investigating and responding to workplace incidents as obligated under Australia's legislation and regulations. Notifiable incidents affecting worker's health and safety are notified to the regulator SafeWork NSW, which can investigate and require corrective action. Incidents involving genetically modified organisms are reported to the Office of the Gene Technology Regulator, and notifiable infections to State health authorities where applicable. An additional overseas obligation to notify NIH within 24 hours of defined significant incidents (including laboratory-acquired infections, potential community releases, BSL-3/4 incidents and compliance violations) would duplicate this chain of reporting, investigation and response, without adding protection to the workers or the community.

Conflicting with other Australian regulations on disclosure: A blanket requirement to publish minutes and incident reports may conflict with existing Australian regulation on security, privacy and commercial confidentiality. For example, work with security sensitive biological agents under Australia's SSBA Scheme is controlled not only at the materials handling but also the information and systems that support it, with vetting required for personnel who have access. Publishing minutes or incident reports that describe agent inventories, facility details, or security gaps would conflict directly with the regulatory requirement. Incident reports involving exposures or infections may also contain health information about identifiable workers, the disclosure of which is restricted under Commonwealth and NSW privacy and health records legislation. While the Draft allows "appropriate and allowable redactions," it does not define what redactions are permitted or whether obligations under foreign laws may override these requirements.

Recommendation: We ask NIH to:

1) Limit mandatory reporting to NIH-supported research and the facilities where it is conducted, rather than all research at any institution with any NIH funding. To support transparency while avoiding local legal and regulatory conflict, there should be a public summary section in the incident and minutes templates, separate from a confidential record, for organisations to fulfill NIH obligation.

2) Specify which redactions are allowed from public posting, and confirm that security, privacy and commercial-confidentiality obligations under Australian law qualify and may override disclosure requirements;

3) Accept a single incident investigation report that satisfies both NIH and the Australian regulators, and tier reporting by severity so that administrative lapses are not on the same 24-hour clock as potential laboratory-acquired infections.

6. Other feedback relevant to this resource: The Draft would apply to all existing awards six months after the final Policy is published, and no covered research may be conducted until NIH has approved an institution's Assurance. This is too short for institutions to establish or adapt committees, agree arrangements with affiliates and obtain approval. The Draft also does not say how institutions outside

the United States obtain an Assurance, or how externally administered or shared IBCs and multi-institution projects are handled. In addition, the Policy adds requirements for biosafety officers, committee administration, training and public posting, while foreign recipients operate under constrained indirect-cost arrangements.

Recommendation: We ask NIH to extend the transition period to 18 - 24 months, with existing IBC approvals continuing until their scheduled renewal; to publish the Assurance process and timelines for foreign recipients, including single-review arrangements for shared IBCs; and to confirm that these compliance costs are allowable on awards to foreign recipients, or acknowledge the unfunded burden.

Uploaded File: NIH-Biosafety-Policy-Draft-feedback-submission-from-the-University-of-Sydney-October-2026.pdf

Description: Submission from The University of Sydney

THE UNIVERSITY OF SYDNEY

SUBMISSION TO THE NATIONAL INSTITUTES OF HEALTH - U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

FEEDBACK TO DRAFT NIH BIOSAFETY POLICY (NOTICE NUMBER: NOT-OD-26-112)

Prepared by: Biosafety – WHS Specialist

EXECUTIVE SUMMARY

The University of Sydney supports NIH's aim of risk-proportionate, transparent and accountable biosafety oversight, and welcomes the opportunity to comment on the Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112). As an Australian institution with researchers who receive NIH funding, and which already operates under national biosafety legislation and institutional policies and procedures, our comments focus on how the Policy would apply outside the United States. We ask NIH to:

1. **Narrow the reach.** Limit mandatory coverage to NIH-supported research and the facilities where it is conducted, rather than all research at any institution with any NIH funding and define what it means for research to be “sponsored by” or conducted “at the institution”.
2. **Recognise Australian regulation and legislation.** Retain the host-country deference in the current NIH Guidelines (Section I-C-1-b(3)) and provide an equivalency (foreign assurance) pathway for institutions already regulated under Australian biosafety and biosecurity law.
3. **Reconcile public posting and incident reporting with local law.** Security, privacy, and commercial-confidentiality obligations must be able to override disclosure requirements. NIH should also accept a single incident report that satisfies both NIH and the Australian regulators.
4. **Allow time and resources to transition.** Extend the transition period to 18–24 months, publish the Assurance process for foreign recipients, and confirm that compliance costs are allowable.
5. **Enable voluntary adoption.** Offer pathways and open access to resources for institutions that are not subject to the Policy.

BACKGROUND

NIH released the Draft NIH Biosafety Policy for public comment on 19 August 2026, with responses due by 19 October 2026. The Policy raises concerns about its scope, unintended consequences and practical implementation for institutions outside the United States. The following sections set out these concerns, each with a recommendation that would give NIH assurance of compliance with its biosafety oversight principles while maintaining collaborative research across jurisdictions.

SCOPE AND REACH OF THE POLICY

Section II applies the Policy to non-NIH-funded research at any institution receiving any NIH funding, and the Compliance and Enforcement provisions require institutions, as a term and condition of NIH funding, to ensure that all research conducted at or sponsored by them complies, whatever the funder. This is a significant change for institutions outside the United States. Under the current NIH Guidelines, the institution-wide requirement applies to research within the U.S. and its territories (Section I-C-1-a), while research performed abroad is covered only where it is supported by NIH funds or involves human testing of NIH-developed materials (Section I-C-1-b), and must comply with host-country rules where they exist (Section I-C-1-b-(3)).The University recognises that the Policy provides a sound framework of fundamental biosafety principles and practices for biomedical research, particularly as a model for institutions outside existing regulatory frameworks. However, it is not clear whether the Policy applies to foreign institutions that collaborate with a U.S. institution receiving NIH funding, or that receive NIH funding and conduct the research outside the U.S. The Draft also does not define “sponsored by” or “at the institution” or say whether an institution that receives NIH funds only as a subaward “receives any NIH funding”. As currently drafted, the Policy would cover an institution’s entire research portfolio, not just the NIH-funded work.

For a large Australian university such as ours, this means a single NIH award could bring work funded by our National Health and Medical Research Council, the Australian Research Council, the Medical Research Future Fund and industry under NIH terms. It could also reach facilities shared with affiliated hospitals and research institutes that the university cannot contractually bind.

Recommendation: We ask NIH to limit mandatory scope to only NIH-supported projects and the laboratories where they are conducted, to define "sponsored by" and "at the institution" (including affiliates, adjuncts and shared facilities), to clarify whether subaward-only funding brings an institution within scope, and to leave wider adoption to the voluntary provisions.

RECOGNITION OF AUSTRALIAN REGULATION ON HANDLING OF BIOHAZARDS

The University supports the Policy’s principle of tiered oversight calibrated to risk. The main gap for an Australian institution is that the Policy does not recognise foreign regulatory systems. The import, export, use, storage and transport of biological materials in Australia are already governed by Federal and State legislation, regulatory schemes, and technical standards. These protect Australian public health and safety, prevent the introduction and spread of infectious diseases and pests, safeguard the environment and give effect to Australia’s international treaty obligations. Non-compliance carries serious consequences including suspension of research, loss of licences and permits, and criminal penalties. Most of the Policy’s scope therefore already has a regulated counterpart in Australia, as the table below shows. Requiring foreign institutions to meet both systems would duplicate processes for the same work without improving safety and runs against the Draft’s stated aim of reducing red tape.

Biological Handling	Legislations/Standards	Biosafety Consideration	Regulator
General exposure to biological hazards at work	Work Health and Safety Act 2011 (NSW) & Work Health and Safety Regulation 2025 (NSW)	Employer's due diligence in minimising worker's exposure to the biological hazards at work	SafeWork NSW [State]
Work involved genetic manipulation or usage of genetically modified organisms (GMOs)	Gene Technology Act 2000 Gene Technology Regulations 2001	Management of unintentional release of biological materials posed by gene technology and genetically modified organisms through regulatory framework of organisation accreditation, facility certification, dealings classification, licensing, monitoring, inspection and reporting. Accredited organisations operate statutory Institutional Biosafety Committees established under the Regulator's guidelines, which assess and supervise dealings.	Office of the Gene Technology Regulator (OGTR), Department of Health [Federal]
Materials listed on Security Sensitive Biological Agents (SSBA) Regulatory Scheme	National Health Security Act 2007 (Cth), Part 3 National Health Security Regulations 2018 (Cth) SSBA Standards	The Scheme aims to designate biological agents that are of security concern to Australia and enforce a regulatory framework that limit opportunities for act of bioterrorism whilst maintain access to SSBAs for those with a legitimate need within secure laboratories.	Australian Centre for Disease Control [Federal]
Import permits for biological materials and subsequent control of materials of biosecurity concern under an Approved Arrangement	Biosecurity Act 2015 (Cth)	Imported biological material is regulated under a permit regime whereby materials are risk assessed for potential impact on the environment and economy. If a risk is found substantial, the material must enter an Approved Arrangement that allow handling under strict conditions of containment protocols, treatments, verification methods, documentation and record keeping. The organisation that handling Approved Arrangement materials is subject to regular, fee-for-service monitoring audits every 6 months.	Department of Agriculture, Fisheries and Forestry [Federal]
Biological materials on Dual-use of Defence &	Defence Trade Controls Act 2012	The Scheme runs on a permit regime under which the supply and brokering of listed human and animal	Defence Export Control, a

Strategic Goods List (DSGL)		pathogens and toxins, including intangible transfers to overseas collaborators is subject to strict conditions and approval by the Regulator. The listing overlaps substantially with the SSBA List and with Risk Group 3 and above organisms.	Commonwealth Regulator [Federal]
Reporting of notifiable infections	Public Health Act 2010 (NSW) and Regulation	Notification obligations relating to scheduled medical conditions, and NSW Health requirements engaging the University where clinical or diagnostic material is handled in shared precinct facilities.	NSW Health [State]
Transport of infectious substances	Australian Dangerous Goods Code and IATA Dangerous Goods Regulations	Classification, packaging, marking, documentation and consignor training for Category A and Category B infectious substances, including all inbound and outbound transfers of high-risk material.	Referenced by all the above regulators
Micro-organisms Risk Group classification and Physical Containment Level classification and requirement (equivalent to BSL 1-4)	AS/NZS 2243.3:2022 *Safety in laboratories, Part 3: Microbiological safety and containment*	The Standard is widely referenced by Australian regulatory instruments and regulators for the risk classification and containment requirements for handling microorganisms, and becomes binding where incorporated into legislation, licence conditions, facility certification or permit conditions.	Referenced by several of the above regulators

The current NIH Guidelines already recognises this. Section I-C-1-b(3) provides that, for NIH-supported research performed abroad, if the host country has established rules for the conduct of recombinant or synthetic nucleic acid research, the research must comply with those rules; only where the host country has no such rules must the research be reviewed by an NIH-approved Institutional Biosafety Committee or equivalent body and accepted by the host country's national authority. The Draft Policy contains no equivalent provision. Australia's Gene Technology Act 2000 already requires accredited organisations to operate Institutional Biosafety Committee under the Regulator's guidelines, so the oversight structure NIH seeks already exists in Australian law.

As currently drafted, research that falls under the "purview of another federal agency" may proceed under that agency's oversight, but this appears limited to U.S. agencies. We ask NIH to extend this recognition to foreign institutions operating within mature, nationally regulatory frameworks, such as Australia's, where equivalent oversight mechanisms already exist.

Recommendation: We ask NIH to retain the host-country deference in Section I-C-1-b(3) of the current NIH Guidelines and to establish an equivalency or foreign assurance pathway, under which institutions may certify compliance with their national biosafety law while committing to the Policy's core principles, including risk assessment before work begins, proportionate biosafety oversight using a tiered review approach, and appropriate containment and approval requirements.

PUBLIC POSTING AND INCIDENT REPORTING OBLIGATIONS

While the University supports transparency and prompt incident reporting, we have concerns about the requirements for an Australian institution.

- Application beyond NIH-funded research is unclear: Section II extends the Policy to non-NIH-funded research at any institution that receives NIH funding, but the posting and reporting requirements do not say whether they follow. It is unclear whether minutes and incident reports covering non-NIH-funded work must be posted or notified to NIH, or whether the requirements apply only to NIH-supported research.
- Duplication of established incident reporting systems: Institutions in Australia already operate established systems for reporting, investigating and responding to workplace incidents as obligated under Australia's legislation and regulations. Notifiable incidents affecting worker's health and safety are notified to the regulator SafeWork NSW, which can investigate and require corrective action. Incidents involving genetically modified organisms are reported to the Office of the Gene Technology Regulator, and notifiable infections to State health authorities where applicable. An additional overseas obligation to notify NIH within 24 hours of defined significant incidents (including laboratory-acquired infections, potential community releases, BSL-3/4 incidents and compliance violations) would duplicate this chain of reporting, investigation and response, without adding protection to the workers or the community.
- Conflicting with other Australian regulations on disclosure: A blanket requirement to publish minutes and incident reports may conflict with existing Australian regulation on security, privacy and commercial confidentiality. For example, work with security sensitive biological agents under Australia's SSBA Scheme is controlled not only at the materials handling but also the information and systems that support it, with vetting required for personnel who have access. Publishing minutes or incident reports that describe agent inventories, facility details, or security gaps would conflict directly with the regulatory requirement. Incident reports involving exposures or infections may also contain health information about identifiable workers, the disclosure of which is restricted under Commonwealth and NSW privacy and health records legislation. While the Draft allows "appropriate and allowable redactions," it does not define what redactions are permitted or whether obligations under foreign laws may override these requirements.

Recommendation: We ask NIH to:

i) Limit mandatory reporting to NIH-supported research and the facilities where it is conducted, rather than all research at any institution with any NIH funding. To support transparency while avoiding local legal and regulatory conflict, there should be a public summary section in the incident and minutes templates, separate from a confidential record, for organisations to fulfill NIH obligation.

ii) Specify which redactions are allowed from public posting, and confirm that security, privacy and commercial-confidentiality obligations under Australian law qualify and may override disclosure requirements;
iii) Accept a single incident investigation report that satisfies both NIH and the Australian regulators, and tier reporting by severity so that administrative lapses are not on the same 24-hour clock as potential laboratory-acquired infections.

TRANSITION, ASSURANCE PROCESS AND COST

The Draft would apply to all existing awards six months after the final Policy is published, and no covered research may be conducted until NIH has approved an institution's Assurance. This is too short for institutions to establish or adapt committees, agree arrangements with affiliates and obtain approval. The Draft also does not say how institutions outside the United States obtain an Assurance, or how externally administered or shared IBCs and multi-institution projects are handled. In addition, the Policy adds requirements for biosafety officers, committee administration, training and public posting, while foreign recipients operate under constrained indirect-cost arrangements.

Recommendation: We ask NIH to extend the transition period to 18 - 24 months, with existing IBC approvals continuing until their scheduled renewal; to publish the Assurance process and timelines for foreign recipients, including single-review arrangements for shared IBCs; and to confirm that these compliance costs are allowable on awards to foreign recipients, or acknowledge the unfunded burden.

ENABLING VOLUNTARY ADOPTION

The University of Sydney welcomes the Policy's intention to serve as a model framework. However, a mandatory institution-wide requirement may discourage voluntary uptake and make international collaborations harder to sustain. Voluntary adoption is more likely if NIH offers a path that accommodates existing national regimes. We suggest:

- A verification of alignment with the Policy's principles, available to institutions that already operate under an accredited national biosafety regime, in place of full Assurance;
- A published self-assessment tool and mapping to international standards (the WHO Laboratory Biosafety Manual, 4th edition, and ISO 35001), so institutions can show equivalence;
- Open access to implementation of resources, training materials and templates for institutions not subject to the Policy, adaptable to local law.

The University value the partnership with the NIH and welcome the opportunity to engage further with NIH's Office of Science Policy as the Biosafety Policy is developed.

523. Kari Seedle

I am responding: On behalf of myself

Name: Kari Seedle

Name of Organization: University of Hawaii

Type of Organization: Academic Institution

Role: Other

Role - Other: IBC Coordinator

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Educational research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: I agree with the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA), but would like to add:

Clarification of Key Definitions: Clearly define foundational terms (e.g. biological agent, toxin, genetic modification, laboratory research, genetically modified organism (GDMO) within the policy to ensure consistent interpretation and compliance across institutions.

Clarify Acronyms: Before adding an acronym, spell it out first.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): I agree with the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA), but would like to add:

There is a typo under IBC Functions in the first bullet: Reviewing research for compliance with the Policy as specified in Section IV" Categories of Oversight for Research Based on Risk" and approving, as warranted, research that meets the requirements of the Policy.
If keeping this sentence, fix to: Reviewing research for compliance with the Policy as specified in Section IV "Categories of Oversight for Research Based on Risk" and approving, as warranted, research that meets the requirements of the Policy.

3. Continued utility of Risk Groups: I agree with the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA), but would like to add:

Implementation Resources & National Risk Database: Develop comprehensive guidance tools, including a national database for Risk Group and containment determinations, to foster consistent, evidence-based risk assessments.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): I agree with the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA), but would like to add:

Recalibration of Public Posting: Adjust public disclosure requirements to balance public transparency with institutional security and administrative feasibility. Public posting of incidents as drafted is likely to discourage prompt reporting. If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. Remove wording that IBC rosters must be publicly-posted.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: I agree with the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA), but would like to add:

24-Month Phased Transition Period: Provide a minimum 24-month phased transition period to enable institutions to update procedures, retrain staff, and adapt administrative systems smoothly. Where appropriate, permit conversion at a significant amendment or schedule d renewal, with safeguards and priority for higher-risk work. Preserving staggered renewal cycles will help to avoid unnecessary backlogs.

Uploaded File: Response-to-Draft-NIH-Biosafety-Policy-KS.docx

Description: I have attached my support to the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA) LINK: https://cdn.ymaws.com/members.cshema.org/resource/resmgr/press-releases/cshema-nih-comments.pdf

19 October 2026

SUBJECT: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Support for CSHEMA Recommendations

To Whom It May Concern:
I am writing to express support for the National Institutes of Health's (NIH) efforts to modernize biosafety oversight and establish a comprehensive, risk-based framework. I appreciate the opportunity to offer feedback on the draft policy.

As an IBC Coordinator my work would be directly impacted by the proposed NIH biosafety policy. I endorse the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA). CSHEMA'S recommendations appropriately reflects the practical needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

While I support CSHEMA's comments in full, I would like to draw particular attention to several priority areas that are vital to our institution's operations:

- **Clarification of Key Definitions:** Clearly define foundational terms (e.g. biological agent, toxin, genetic modification, laboratory research, genetically modified organism (GDMO) within the policy to ensure consistent interpretation and compliance across institutions.

- **Recalibration of Public Posting:** Adjust public disclosure requirements to balance public transparency with institutional security and administrative feasibility. Public posting of incidents as drafted is likely to discourage prompt reporting. If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. Remove wording that IBC rosters must be publicly-posted.

- **Implementation Resources & National Risk Database:** Develop comprehensive guidance tools, including a national database for Risk Group and containment determinations, to foster consistent, evidence-based risk assessments.

- **24-Month Phased Transition Period:** Provide a minimum 24-month phased transition period to enable institutions to update procedures, retrain staff, and adapt administrative systems smoothly. Where appropriate, permit conversion at a significant amendment or schedule d renewal, with safeguards and priority for higher-risk work. Preserving staggered renewal cycles will help to avoid unnecessary backlogs.

Thank you for your consideration of these comments and for your commitment to advancing biosafety oversight.

Sincerely,



Kari Seedle
Biosafety Program Specialist
IBC Coordinator

524. Washington State University

I am responding: On behalf of an organization

Name: Jacob Dowd

Name of Organization: Washington State University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Washington State University, a public land-grant research university with a broad portfolio spanning biomedical, agricultural, environmental, and life sciences research, WSU has a strong interest in ensuring that biosafety policies effectively support both scientific advancement and responsible oversight.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: WSU-Comments-NIH-Biosafety-Policy-for-Research-Involving-Biohazards-10.13.2026.pdf

Description: WSU Comments on NIH Biosafety Policy for Research Involving Biohazards

WASHINGTON STATE UNIVERSITY

Office of Research Assurances

ELECTRONIC DELIVERY

October 19, 2026

Dear National Institute of Health, Office of Science Policy,

On behalf of Washington State University (WSU), we appreciate the opportunity to provide comments on the proposed Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112). As a public land-grant research university with a broad portfolio spanning biomedical, agricultural, environmental, and life sciences research, WSU has a strong interest in ensuring that biosafety policies effectively support both scientific advancement and responsible oversight.

WSU recognizes NIH's efforts to modernize and consolidate biosafety requirements through the development of a new policy framework intended to replace the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. We support the goals of maintaining robust biosafety practices, promoting public trust in the research enterprise, and providing institutions with clear expectations for the oversight of research involving biological hazards.

Because the proposed policy would establish new requirements affecting institutional governance, investigator responsibilities, reporting practices, and biosafety review processes, it will have substantial implications for the administration of research programs across the academic community and for the researchers themselves. WSU has reviewed the proposal with particular attention to provisions that may affect the effectiveness of biosafety oversight, consistency of implementation, and the administrative resources required to achieve compliance, as well as the impact on the Principal Investigator and research teams.

WSU supports the biosafety community comments included within R. Moritz et. al. document titled “A White Paper on Finalizing and Implementing the Proposed NIH Biosafety Policy.” The comments below are in addition to this document and identify areas where additional clarification or modification would improve the policy's effectiveness while continuing to support NIH's objectives of protecting researchers, the public, and the environment.

Section II

Scope: The draft policy extends oversight beyond recombinant or synthetic nucleic acid research to include wild-type biological agents that cause human disease but omits pathogens that affect only animals or plants. The addition of wild-type organisms previously outside the scope of the NIH guidelines may add significant burden to institution’s IBC review volume. WSU recommends the NIH to identify frameworks for non-zoonotic animal-pathogen oversight.

Plants: As a land-grant institution with a significant agricultural research portfolio, WSU conducts and oversees numerous projects involving genetically modified plants. WSU is

concerned that excluding genetically modified plants from the scope of the proposed policy may create gaps in biosafety oversight and risk management.

Although current research involving genetically modified plants or modified microorganisms associated with plants is conducted under established containment and stewardship practices, potential loss of containment remains a concern. Such events could result in environmental impacts, economic consequences, and reputational harm to research institutions and the broader research enterprise. WSU believes that including genetically modified plants within the policy would promote a more comprehensive and consistent approach to biosafety oversight across federally funded research activities.

For consistency, WSU therefore recommends that the IBC Membership section include the requirement of a plant expert on the IBC when institutions conduct plant research that falls within the policy's scope. Furthermore, in the Laboratory Research section, WSU recommends explicitly incorporating Plant Biosafety Levels within the definition of laboratory research. Doing so would help ensure that plant research activities are appropriately addressed within the policy framework and that containment standards are applied consistently across research systems. Finally, in Section IV-2 Research That Requires IBC Review and Approval Before Initiation, WSU recommends removing the language that exempts genetically modified plants and plant cells.

Toxin: WSU seeks clarification as to the proposed definition of toxin as protein-based, as it may be interpreted too narrowly. The definition does not expressly account for biologically derived, non-proteinaceous toxins that may pose significant risks to human and animal health. Examples include, but are not limited to, saxitoxin, lipopolysaccharide (LPS), and tetrodotoxin. These substances can present substantial hazards despite not being protein-based and should be considered within the policy's risk management framework.

Section III-A/B/C

Incident Reporting: WSU is concerned that requiring incident reports to be posted on publicly accessible websites using the proposed template creates unintended risks to Principal Investigator and researcher safety and privacy. The goals associated with this transparency are most effectively obtained when the information disclosed enhances public understanding, accountability, and confidence in the oversight process. The requirement of routine publication of investigator names, grant numbers, internal project numbers, sensitive animal information, select agent information, proprietary research details, identifying facility information, or other details likely compromises safety, security, or personnel protection. Furthermore, public disclosure requirements of this nature may have a chilling effect on incident reporting. Institutions and investigators may be less willing to report incidents promptly and comprehensively if doing so results in broad public dissemination of investigator-specific information.

Minutes: Similarly, WSU is concerned that requiring institutions to use the proposed meeting minutes template as written would substantially increase administrative burden for IBC staff while providing information that is largely duplicative of existing IBC review and documentation practices. Furthermore, certain requirements may create unnecessary risks to Principal Investigator privacy and safety. Specifically, the proposed template requires inclusion of PI names, Project Overview, Risk Assessment and Discussion, and Occupational Health Representative Review. These elements are largely redundant within

meeting minutes, as a comprehensive risk assessment already incorporates project-specific information, including an overview of the research and relevant occupational health considerations. Requiring these topics to be documented separately in meeting minutes would duplicate information already reviewed and maintained as part of the protocol review process without providing significant additional value. Furthermore, the proposed policy requires research protocols to include risk assessments, and those protocols may be subject to disclosure through public records processes. If the intent is to enhance transparency and public trust, WSU notes that existing IBC composition requirements already address this objective by requiring community representatives who are responsible for representing the interests of the surrounding community with respect to public health and environmental protection. WSU recommends template flexibility, including the following sections as optional rather than mandatory elements: Project Overview, Risk Assessment and Discussion, and Occupational Health Representative Review.

WSU recommends further clarification on allowable redactions, namely deidentification of people and details that compromise safety and security, for both publicly posted Incident Reports and Minutes.

Record Retention: WSU notes that the proposed policy requires institutions to maintain all IBC records for three years following submission of the final financial report, consistent with 2 CFR 200.334. However, the proposal also requires that IBC meeting minutes be retained for a minimum of five years to comply with NIH Grants Policy Statement requirements. Clarification between these standards would ensure greater compliance.

Initial submission, Periodic, and *de novo* protocol review: The proposed requirement for research protocols to undergo *de novo* review every three years in addition to periodic reviews is unclear. Under current practices, IBC protocols are generally maintained as living documents that are continuously updated as research activities evolve. Protocols are typically subject to periodic renewal and ongoing review, allowing committees to evaluate significant modifications, changes in risk, and continuing compliance throughout the life of a project. This approach provides sustained oversight while avoiding unnecessary duplication of effort. Implementation guidance for currently approved protocols and whether they would need to be reviewed again or be grandfathered until renewal is also needed.

Biological Safety Officer (BSO): WSU recognizes the important role that the Biological Safety Officer plays in supporting institutional biosafety programs and ensuring compliance with biosafety requirements. However, WSU is concerned that the proposed responsibilities outlined in this section appear to assume that all BSO functions must be performed by a single individual. At many institutions, effective biosafety oversight is achieved through a team-based approach in which responsibilities are appropriately shared among associate BSOs, biosafety professionals, and other qualified personnel. Delegation helps ensure continuity of operations, promotes timely completion of required activities, and reflects the organizational structures commonly used to support modern research programs. Additionally, the provision that institutions that do not designate a BSO must assign another official to fulfill BSO responsibilities lacks clarity. Without clearly defined minimum qualifications, institutions may face uncertainty regarding compliance expectations and the level of expertise necessary to adequately perform these responsibilities. Accordingly, WSU recommends adding language that explicitly permits the delegation of appropriate responsibilities to qualified designees under the oversight of a designated BSO. WSU further

recommends establishing minimum qualifications and competency expectations for any alternate official designated to perform BSO responsibilities when a BSO has not been appointed.

Principal Investigator (PI): WSU requests clarification regarding the final paragraph of this section, which encourages the submission of reports concerning near-misses, secondary containment failures, and procedural issues to the National Biosafety Data and Safety Analysis Center (NBDSAC). As written, it is unclear whether the policy intends Principal Investigators to submit such reports directly, or whether the recommendation is directed toward institutions through their Institutional Biosafety Committees (IBCs) or other institutional oversight mechanisms. The paragraph references “institutions,” but its placement within the section describing PI responsibilities creates ambiguity regarding who is responsible for reporting and under what circumstances. Clarification of what information should be submitted to NBDSAC, how these should be redacted or de-identified, who may access this identifiable information, and whether and how records may be disclosed. It should also be clarified that this voluntary reporting remains separate from mandatory compliance reporting.

Section IV
Research That Requires Review and Approval Before Initiation and May Be Delegated to an Individual or Subgroup of IBC Members: Clarification of research criteria permissible under a designated review model versus full committee would ensure compliance with the policy. Without clearly defined criteria, institutions may apply differing risk thresholds when determining whether research qualifies for delegated review. This variability could create uncertainty for investigators and oversight committees and may result in inconsistent levels of review for research activities with similar risk profiles. WSU is concerned that the terms “low-risk transgenes” and “well-characterized cell lines” are not clearly defined within the proposed policy. Because these categories may be used to determine eligibility for delegated review, ambiguity in their definitions could result in inconsistent interpretation and implementation across institutions. Additionally, a definition of “clinical research” is needed to ensure all activities have proper oversight. WSU recommends that the policy provide clear, objective, and risk-based definitions for “low-risk transgenes.” For example, the policy could specify characteristics that would exclude a transgene from this category, such as transgenes encoding oncogenic factors, clinically relevant antibiotic resistance determinants, toxins, or other products that could reasonably increase risks to human health, animals, plants, or the environment. Similarly, WSU recommends that the policy define what constitutes a “well-characterized cell line,” including the minimum information or documentation necessary to establish a cell line's origin, properties, history of use, and associated risk profile. Clear criteria would help ensure consistent application of delegated review processes across institutions and provide greater transparency for investigators and oversight committees.

Conclusion
WSU supports NIH's commitment to maintaining a strong and effective framework for biosafety oversight and appreciates the effort invested in developing a modernized policy for research involving biohazards. The proposed policy presents an important opportunity to strengthen institutional biosafety programs while promoting consistency, transparency, and public confidence in federally supported research. WSU believes that well-defined requirements and appropriately tailored oversight mechanisms will enhance institutional

compliance and allow biosafety resources to remain focused on activities that present the greatest risks.

We appreciate NIH's willingness to engage with the research community during this process and welcome continued dialogue on the development of a practical, effective, and science-based biosafety framework. Thank you for the opportunity to provide comments on the proposed policy.

Sincerely,
Washington State University

525. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Policy Comments:

The definition of a "biological agent" as any bacteria, viruses, fungi or parasites that specifically causes human disease does not align with current scientific terminology in use. This term and definition has the potential to cause extensive confusion when compliance/safety personnel communicate with the broader scientific community and should be revised.

Mandatory de novo review required specifically at three years would substantially increase workload for many investigators, BSOs, IBC staff, committee members, and institutional officials. Permit IBC approvals for up to five years which has been commonly utilized in this field. Authorize temporary administrative extensions for currently approved work when a subsequent a de novo institutional review is in progress.

Permit delegated review when primary cells may contain an RG2 agent, consistent with the delegated-review pathway for work conducted directly with wild-type RG2 biological agents.

Define what information must be included for a delegated approval to be “reported in full.” Permit institutions to report each delegated approval using information such as institutional registration number, general research category, type of submission or amendment, broad biological materials, containment level, approval date, and material conditions with opportunity for committee discussion and request for full review.

NIH should also establish a process for publishing and reusing its RG determinations. The draft requires NIH to publish approved lower-containment determinations for RG3 and RG4 agents, but it is less explicit about publishing all determinations for emerging, novel, or zoonotic agents. NIH should maintain a searchable repository that institutions may rely upon when proposed work involves the same agent or a materially equivalent agent, construct, attenuation, and experimental procedure.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Comments on Incident Reporting :

Limit reporting of facility or equipment failures to failures that compromise containment and/or create a risk to personnel, the public, or the environment. The current language is overly broad. Clarify that failure of any single component of facility or equipment does not constitute a reportable event when redundant containment systems or strategies function as intended and no release or potential exposure occurs. A failure of a component or equipment does not necessarily result in a loss of containment or potential exposure, particularly when redundant systems and strategies function as designed by the institution. This is the purpose of these risk mitigation systems and strategies and is a reflection that they functioned correctly. Notification and reporting should focus on failures that compromise containment and/or create a risk to personnel, the public, or the environment.

Remove the requirement for institutions to publicly post PI name and specific grant identifiers for incidents. Effective biosafety programs depend on prompt reporting, candid investigation, and meaningful analysis of contributing factors. Public disclosure of overly detailed project specific identifiers such as those mentioned may permit public identification of affected individuals (especially for small research groups) even when specific personnel identifiers are removed and may discourage personnel from reporting due to negative consequences of public identification.

Limit federally reportable compliance violations to substantive violations that materially compromise biosafety oversight or result in covered research being conducted without required approval or containment. Permit institutions to document and correct minor administrative discrepancies without immediate federal notification when the discrepancy does not affect safety or oversight.

Start the 24-hour notification period when the BSO, IBC Chair, IBC office, institutional official, or another designated institutional authority has sufficient information to reasonably determine that the event meets NIH reporting criteria and require the initial notification to include only information reasonably available at the time of reporting.

6. Other feedback relevant to this resource: N/A

526. Nancy Connell

I am responding: On behalf of myself

Name: Nancy Connell

Name of Organization: Rutgers University (Rutgers NewJersey Medical School)

Type of Organization: Academic Institution

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): infectious disease research (pathogenesis, drug discovery, medical countermeasures); science policy; biosafety and biosecurity

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The proposed scope is limited by its focus on known or potential risk to human health. Plants, animals and their relationship to the environment -and to humans - are not addressed. How will NIH coordinate with other agencies? Will the gaps in oversight be filled? Furthermore, what exactly is meant by "known or potential risk to human health"? Is the institution responsible for evaluating and positioning research with respect to the "threshold" vs the enumerated biohazard categories? In other words, it is not clear whether "relatively low-risk research, including genetically modiied RG1 biological agents, BSL-1/ABSL-1 transgenic organisms,
well-characterized cell lines, and certain plasmids and low-risk transgenes" must also be determined to pose risk to human health, or whether just including some of these biohazards means the research is covered. If the latter is the case, there will be huge increase in oversight infrastructure and many universities and colleges will be unable to accommodate this kind of work. This would be a real loss to the scientific enterprise as a whole, as labs begin to shut down one by one.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: Risk Groups should not serve as a classification that drives laboratory oversight for the following reasons:
• The RGs describe risk to healthy adults in the community and are purported to reflect the potential effect on a healthy human adult. In a laboratory, no one can verify that a oworker is healthy, and some individuals are more susceptible because of
medications, immune status, or pregnancy.
• They reflect community exposure, not laboratory conditions. Laboratory concentrations, volumes, and manipulations differ greatly from what occurs in the
community or environment.
• They have no baseline for novel constructs. Recombinant and synthetic nucleic acid work and synthetic cells do not exist in the community until they have been studied in the laboratory,
• They cover only human etiologic agents. The Policy’s definition of biohazards is broader than agents

that cause human disease, so RGs cannot be the basis for classifying biohazardous material.
• They are misinterpreted. Researchers and Federal agencies treat the RG number as a containment requirement. This becomes a potential safety issue for laboratory
personnel and for the environment outside the laboratory.
In fact, the policy appears to conflate RG with biosafety level.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: There is no clear biosafety or public safety rationale provided to clarify the public interest or biosafety rationale for requiring PI identification in individual incident reports. NIH should consider whether such identification is necessary when it does not materially contribute to understanding or
preventing these incidents.
Publication of IBC minutes could compromise the privacy scientists and other workers, and may also reveal over time important scientific intellectual property.

6. Other feedback relevant to this resource: N/A

527. Kansas State University

I am responding: On behalf of an organization

Name: Natalia Costa Ball

Name of Organization: Kansas State University

Type of Organization: Academic Institution

Role: Other

Role - Other: Institutional Biosafety Officer

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Kansas State University

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Description: Comments on the draft NIH Biosafety Policy for Research Involving Biohazards

528. Alliance for Vision Research

I am responding: On behalf of an organization

Name: Dan Ignaszewski

Name of Organization: Alliance for Vision Research

Type of Organization: Research Participant/Patient Advocacy Organization/Patient Advocate/Caregiver

Role: Organizational Official

Date Submitted: 10/19/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Vision/eye research

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: Please see attached response

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): Please see attached response

3. Continued utility of Risk Groups: Please see attached response

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): Please see attached response

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Please see attached response

6. Other feedback relevant to this resource: Please see attached response

Uploaded File: Alliance-for-Vision-Research-NIH-Biosafety-Comments-Final.pdf

Description: Alliance for Vision Research Response to RFI

October 19, 2026

Jay Bhattacharya, MD, PhD
Director
Office of the Director
National Institutes of Health
1 Center Drive MSC 0122
Bethesda, MD 20892

RE: Comments on Draft NIH Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112)

Dear Director Bhattacharya:

On behalf of the Alliance for Vision Research, we appreciate the opportunity to submit comments on the National Institutes of Health (NIH) Draft Biosafety Policy for Research Involving Biohazards (NOT-OD-26-112).

The Alliance for Vision Research is a national nonprofit advocacy organization dedicated to advancing federal investment in vision research and championing policies that accelerate scientific discovery, foster innovation, and support the development and delivery of new treatments and cures for blinding eye diseases and vision disorders. We strongly support rigorous biosafety protections, responsible institutional oversight, transparency, and NIH's efforts to modernize a framework historically focused on recombinant and synthetic nucleic acid research. We also welcome NIH's stated objective of reducing unnecessary oversight for lower-risk research.

However, the Alliance is concerned that several provisions, unless further defined and refined, could subject routinely conducted, appropriately controlled research to requirements disproportionate to its actual biological risks. An effective policy should distinguish meaningful, reasonably anticipated hazards from theoretical possibilities; establish clear and consistent oversight pathways; and protect both safety and the continuity of valuable biomedical research.

These distinctions are especially consequential for vision research, which relies on a diverse range of human- and animal-derived approaches—including genetically modified mice and zebrafish, donor ocular tissues, primary retinal and anterior-segment cells, retinal organoids, and gene-delivery technologies. Their risks vary according to the source and characteristics of materials, experimental manipulation, potential routes of exposure, and containment measures. The use of a particular model or genetic modification should not, by itself, be treated as evidence of a significant human-health hazard.

Clarify Policy Scope and Apply Risk-Proportionate Oversight (Sections II and IV)

The draft's institutional applicability may extend to research conducted at NIH-supported institutions even when individual projects receive private or other non-NIH funding. NIH should clarify its application to privately sponsored studies, collaborations, shared facilities, and institutional storerooms, including how relevant state requirements and existing federal oversight intersect with the new policy. Institutions need clear guidance about which activities require full Institutional Biosafety Committee (IBC) review and which may be addressed through documented institutional assessment or delegated review.

NIH should provide practical examples for commonly used vision-science methods, including well-characterized, low-risk genetically modified animals, human-derived cells and tissues, and nonreplicating gene-delivery systems. These examples should establish a consistent, risk-based approach without imposing new review requirements solely because a model involves genetic modification or a particular biological source.

Define Adventitious Agents and Appropriate Thresholds for Primary Cells (Section IV-2)

The Alliance is particularly concerned about the proposed coverage of "primary cells that may be contaminated by adventitious agents." Without a definition of "adventitious agent" or a meaningful risk threshold, this language could be interpreted to encompass nearly any primary human or animal cell or tissue for which the absence of every conceivable agent has not been conclusively demonstrated. In vision research, that could include donor-derived retinal tissue, retinal pigment epithelial or corneal cells, patient-derived ocular specimens, and nonhuman primate cells and tissues.

Certain biological specimens warrant heightened precautions. Nevertheless, a purely hypothetical possibility of contamination should not automatically trigger full-committee review. NIH should distinguish known or reasonably anticipated hazards from remote or theoretical possibilities and explain how donor screening, testing, specimen provenance, supplier documentation, handling conditions, and plausible exposure pathways inform the assessment. Eye banks supplying donor ocular tissue for corneal transplantation already operate under applicable federal infectious-disease screening and testing requirements; relevant documentation and safeguards should be appropriately recognized rather than unnecessarily duplicated.

The final policy should specifically address commercially supplied primary cells, specimens held in institutional storerooms or repositories, patient-derived material, primary animal tissues, and nonhuman primate material, recognizing that risks differ by source and species. NIH should identify examples of materials that are included and excluded, allow appropriately documented low-risk activities to proceed through delegated review, and clarify how screening and source documentation contribute to a comprehensive biosafety assessment.

This clarification is particularly important as NIH encourages human-based research and New Approach Methodologies (NAMs). An expansive interpretation of the primary-cell provision could inadvertently discourage the use of organoids, tissue-based disease models, and other emerging methodologies, creating delays and administrative costs without a corresponding, demonstrated safety benefit.

Coordinate Oversight for Animal Models and Existing Institutional Requirements

Genetically modified mice and zebrafish remain important for investigating retinal development, inherited and age-related retinal degeneration, glaucoma, dry eye disease, optic nerve injury, and visual recovery. Where hazards are well characterized and containment is appropriate, streamlined review should be available. NIH should support coordinated documentation and clearly distinguish IBC responsibilities for biosafety from institutional animal-care and animal-welfare oversight to avoid unnecessary duplication or recurring approvals for low-risk activities.

The final policy should also distinguish routine husbandry incidents from events that present a meaningful biosafety concern. Aligning these processes would preserve protections while limiting delays to research conducted under established safeguards.

Support Human-Derived Models, Gene Delivery, and Translational Research

Human retinal organoids, induced pluripotent stem-cell-derived systems, gene-edited cell models, and viral and nonviral delivery tools are essential to understanding disease mechanisms and evaluating promising therapies. Oversight should reflect whether biological material is infectious or replication-competent, whether experimental manipulation meaningfully changes risk, and whether a plausible route of exposure exists—not simply the presence of gene editing or a delivery platform.

NIH should publish examples of appropriately characterized cell systems and delivery approaches eligible for streamlined or delegated review. Consistent expectations across institutions and approved international collaborations would be particularly valuable for multisite research and early-career investigators who are less equipped to absorb unpredictable administrative requirements.

Promote Transparency Without Compromising Research Security (Section III)

The Alliance supports public accountability and meaningful reporting of biosafety incidents. However, requirements to publicly post IBC minutes and incident reports should include clear, standardized safeguards for personnel privacy, unpublished findings, proprietary techniques, sensitive facility information, and research security. NIH should establish uniform redaction standards and permit public summaries where disclosure of detailed records would not meaningfully improve public understanding.

Similarly, reporting thresholds should differentiate serious or potentially consequential incidents from minor, contained events appropriately handled through routine institutional processes. Reporting requirements should encourage prompt internal disclosure, corrective action, and institutional learning, rather than create disincentives to report or permit routine laboratory occurrences to be mischaracterized as substantial safety failures.

Allow Realistic Implementation and Proportionate Compliance (Sections II–V)

The proposed six-month implementation period may be insufficient for institutions to revise policies, expand IBC capacity, train investigators and staff, and harmonize oversight across funding sources. NIH should evaluate administrative burden, staffing, operational costs, and institutional readiness, and provide model procedures, templates, training, and practical examples

before implementation. A longer, phased transition would better position institutions to implement the policy effectively and consistently.

NIH should also calibrate compliance actions to the nature and severity of a violation, the actual risk posed, and the adequacy of corrective action. Isolated, minor procedural lapses should not automatically jeopardize unrelated NIH-supported awards or disrupt laboratories, trainees, clinical research, and patients who depend on the continuity of vision research.

Finally, NIH should explicitly address whether the policy applies retroactively to collections of cells or tissues obtained before its effective date, particularly materials that have been used safely for years. NIH should specify any additional screening, documentation, or review obligations for existing collections and account for the risk of disrupting ongoing studies or rendering valuable research resources impractical to use.

Recommendations

To advance NIH's biosafety objectives while sustaining rigorous and innovative biomedical research, the Alliance for Vision Research respectfully recommends that NIH:

1. Define "adventitious agent" and establish clear thresholds tied to known or reasonably anticipated human-health risks for primary human and animal cells and tissues, with practical included-and-excluded examples.
2. Provide explicit delegated or streamlined pathways for appropriately characterized low-risk primary tissues, cell models, genetically modified animals, and gene-delivery systems.
3. Clarify the policy's reach across funding sources, shared institutional facilities, and collaborations, while recognizing applicable federal, state, and institutional oversight.
4. Coordinate IBC responsibilities with existing animal-care and other institutional review processes, avoiding duplicative documentation and ongoing approvals where risks are already well characterized.
5. Establish consistent standards for public disclosure, redaction, and incident reporting that protect research security and distinguish consequential biosafety events from minor or routine incidents.
6. Provide implementation tools, training, realistic burden and cost assessments, and a longer, phased transition that reflects institutional capacity and readiness.
7. Adopt risk-proportionate enforcement and meaningful opportunities for corrective action so minor violations do not unnecessarily interrupt unrelated ongoing NIH-funded research.
8. Clarify whether and how the policy applies to previously collected cells and tissues, including any retrospective documentation, testing, or review requirements, to protect continuity of established research.

The Alliance for Vision Research shares NIH's commitment to protecting research personnel and the public while maintaining confidence in the integrity of the biomedical research enterprise. These goals are fully compatible with clearly defined, scientifically grounded biosafety standards that apply oversight in proportion to actual risk. For patients and families affected by blinding eye diseases and vision disorders, avoidable delays in research can ultimately delay the discoveries and therapies they are waiting for.

We respectfully urge NIH to refine the proposed policy and accompanying guidance to ensure that strong biosafety protections do not unintentionally create unnecessary barriers to well-characterized animal- and human-based research, including the innovative methodologies NIH seeks to advance. By providing clearer definitions, consistent risk assessments, streamlined review where appropriate, and realistic implementation expectations, NIH can strengthen both laboratory safety and the nation's ability to advance vision research.

Thank you for the opportunity to provide comments on this important proposal. If you have questions or would like to discuss these recommendations, please contact me at 202-742-1885 or dan@eyeresearch.org. The Alliance for Vision Research welcomes continued engagement with NIH and the research community as the policy and implementing guidance are finalized.

Sincerely,

[redacted]

Dan Ignaszewski
Executive Director
Alliance for Vision Research

529. Paul M. Fox, Ph.D.

I am responding: On behalf of myself

Name: Paul M. Fox, Ph.D.

Name of Organization:

Type of Organization: Not Applicable

Role: Institutional Review Oversight Committee Member

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Comment-on-the-Draft-NIH-Biosafety-Policy-for-Research-Invovlving-BiohazardsFox.docx

16 October 2026

SUBJECT: Comment on NIH Effort to Modernize and Strengthen Biosafety Oversight – Support for CSHEMA Recommendations

To Whom It May Concern:
I am writing to express support for the National Institutes of Health's (NIH) efforts to modernize biosafety oversight and establish a comprehensive, risk-based framework. I appreciate the opportunity to offer feedback on the draft policy.

As a community member of the University of Hawaii IBC, my work with the IBC will be impacted by the proposed NIH biosafety policy. I endorse the comments submitted by the Campus Safety, Health, and Environmental Management Association (CSHEMA). CSHEMA'S recommendations appropriately reflects the practical needs and perspectives of higher education and research institutions working to maintain safe, compliant biosafety programs.

While I support CSHEMA's comments in full, I would like to draw particular attention to several priority areas that are vital to our institution's operations:

- **Clarification of Key Definitions:** Clearly define foundational terms (e.g. biological agent, toxin, genetic modification, laboratory research, genetically modified organism (GDMO) within the policy to ensure consistent interpretation and compliance across institutions.

- **Recalibration of Public Posting:** Adjust public disclosure requirements to balance public transparency with institutional security and administrative feasibility. Public posting of incidents as drafted is likely to discourage prompt reporting. If public posting is retained, NIH should allow redaction of PI names, grant identifiers, and other redactions necessary for the protection of proprietary and security-sensitive information. Remove wording that IBC rosters must be publicly-posted.

- **Implementation Resources & National Risk Database:** Develop comprehensive guidance tools, including a national database for Risk Group and containment determinations, to foster consistent, evidence-based risk assessments.

- **24-Month Phased Transition Period:** Provide a minimum 24-month phased transition period to enable institutions to update procedures, retrain staff, and adapt administrative systems smoothly. Where appropriate, permit conversion at a significant amendment or schedule d renewal, with safeguards and priority for higher-risk work. Preserving staggered renewal cycles will help to avoid unnecessary backlogs.

Thank you for your consideration of these comments and for your commitment to advancing biosafety oversight.

Sincerely,

Paul M. Fox, Ph.D.
Hawaii Dept. of Health
State Laboratories Division
Pearl City, HI 96782
paul.fox@doh.hawaii.gov

530. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy should address genetically modified plants (specifically greenhouse work), plant-associated harmful organisms, genetically modified plant pathogens, animal only pathogens (non-zoonotic), and work with agricultural animal in a research setting. There should also be clarity on where the USDA or other federal agencies have oversight that satisfy NIH policy on biosafety and how the IBC should mange such overlap.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

531. N/A

I am responding: On behalf of myself

Name:

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): The expansion of the proposed policy to require NIH approval on emerging, novel, or zoonotic agents that lack a Risk Group classification or containment level according to the BMBL for material otherwise handled at BSL-1 or -2 will be a huge burden on local institutions and IBCs and extremely hard to manage or capture. Some of these agents come up during routine screenings or when using gene libraries to find an intended product but produce other side mutations that are unwanted and then discarded. The Policy should allow local IBCs with SMEs to make these risk assessments and determinations whether further NIH review is needed, such as when there is significant environmental consequences.

3. Continued utility of Risk Groups: Well characterized human cell lines are either captured under OSHAs BBP Standard or have been downgraded to safely handle at BSL-1 under set parameters. The policy could add such parameters, such as required testing for BBP and cell banking. Following vetted downgrade guidelines should not require additional IBC or NIH review. There is no additional risk assessment required for human cells beyond an initial assessment to identify source and potential contamination risk. Most modified human cells don't pose an additional risk beyond that. Requiring all well characterized human cell lines to be registered separately is a huge administrative burden that would more harm the biosafety program and provide any benefit.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Review by NIH of minor incidents that are then required to be publicly posted seems more punitive than helpful. Low-risk incidents and near misses should be managed thru the local IBC and biosafety program to encourage such reporting by researchers to the biosafety team, which then follows up, learns from, and instructs to avoid such incidents in the future. Requiring the publication of such incidents will cause lab staff to rather not report for fear of retribution.

6. Other feedback relevant to this resource: N/A

532. Marie-Luise Faber

I am responding: On behalf of myself

Name: Marie-Luise Faber

Name of Organization:

Type of Organization: Not Applicable

Role: Member of the Public

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: The policy does not address current work that has been approved by IBCs or biosafety programs at institutions. Will the policy only focus on research and new material being brought in after the final draft or will existing research also fall under the new policy. If that later is to be implemented, how will this be done. Will existing exemptions issues under the NIH Guidelines be kept in place? Will new risk determinations by the NIH apply to all institutions, as they have in the past, or will each institution or lab be required to apply for approval or exemption? The proposed policy reaches far beyond what most IBC register today. How will this existing material and research be folded into the new policy?

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: Federal funding is needed to support this policy if it is to be successful and robust. The NIH needs to pilot pieces of the new policy, such as meeting minutes, incident reporting systems, and delegated review tools, by working with large and small institutions, rural and urban, or resource rich and poor to see what works best and what customization is needed for varying institutions to achieve a uniform outcome. There will also be a need for additional training of biosafety professionals to adapt new requirements to current research. The NIH will need to assess the cost and impact of the new policy on al the entities listed above before requiring implementation.

533. La Trobe University

I am responding: On behalf of an organization

Name: Alistair Duncan

Name of Organization: La Trobe University

Type of Organization: Academic Institution

Role: Organizational Official

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): La Trobe University's research portfolio covers a broad range of disciplines, including biomedical, microbiological, infectious disease, molecular and cell biology, agricultural, veterinary, environmental, and biotechnology research.

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: La Trobe University supports NIH's objective of strengthening and modernizing biosafety oversight for research involving biohazards. For international institutions, however, clarification is needed regarding the scope of application. The draft policy appears capable of extending oversight obligations beyond NIH-funded activities to broader institutional research programs. We recommend that the policy apply to NIH-funded research and activities that directly support or are materially connected with NIH-funded research. Australian universities already operate under mature statutory and institutional biosafety systems, including the Australian Gene Technology Scheme, biosecurity legislation, institutional biosafety committee oversight, and Australian/New Zealand standards for microbiological safety and containment. Where institutions operate within established national biosafety frameworks, the policy should recognize equivalent biosafety outcomes rather than requiring duplication of US-specific requirements. NIH should also provide clear guidance on how the policy applies to foreign recipients, subrecipients and collaborators, particularly where domestic legal or regulatory requirements differ from NIH requirements.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): La Trobe University supports a tiered, risk-based oversight model that calibrates requirements according to the level of biosafety risk. We encourage NIH to ensure that oversight remains proportionate and avoids imposing unnecessary administrative requirements on lower-risk activities or research already subject to robust oversight under established national regulatory systems. For international institutions operating within mature biosafety frameworks, local oversight mechanisms should play a primary role, with additional federal requirements focused on areas of elevated risk or where specific NIH interests require additional assurance. A risk-based approach should minimise duplication while maintaining high biosafety standards.

3. Continued utility of Risk Groups: Risk Groups remain a useful reference point for assessing intrinsic agent hazards; however, containment and operational requirements are ultimately implemented through facility and procedural controls. For institutions outside the United States, it is important that NIH provide guidance on how alternative classification systems relate to the proposed framework. Australian institutions typically use Physical Containment (PC) classifications rather than Biosafety Levels (BSL). NIH should therefore clarify how PC levels, Risk Groups, BSL and ABSL classifications align for the purposes of compliance and oversight. Such guidance would improve consistency and reduce the risk of unnecessary duplication or conflicting interpretations.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should consider establishing a foreign-assurance or equivalency pathway for institutions operating under mature domestic biosafety systems. Under such a framework, institutions could demonstrate that their regulatory environment and internal governance arrangements achieve biosafety outcomes comparable to NIH expectations without requiring full duplication of US-specific processes, terminology or committee structures. A proportionate assurance mechanism would encourage continued participation by international collaborators while maintaining appropriate accountability and biosafety standards.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: The draft templates appear useful for promoting consistency and transparency. For international institutions, NIH should consider allowing reasonable flexibility where local reporting frameworks, incident notification requirements, recordkeeping standards or committee procedures differ from US practice. The templates should be positioned as models that can accommodate equivalent information generated through established institutional and national systems. This approach would reduce unnecessary administrative burden while preserving the intent of consistent reporting and oversight.

6. Other feedback relevant to this resource: Additional guidance would be particularly valuable for foreign recipients and collaborating institutions. Priority areas include: Clarification of the scope of activities covered by the policy. Criteria for determining when research is materially connected to NIH funding. Guidance on managing conflicts between NIH requirements and domestic legal obligations. Mapping of international biosafety classification systems, including Australian Physical Containment levels, against NIH Risk Groups and Biosafety Levels. Development of a foreign-assurance or equivalency framework. Worked examples involving institutions with mixed NIH-funded and non-NIH-funded research portfolios. A reasonable transition period to enable institutions to assess impacts and implement any required governance changes.

Uploaded File: La-Trobe-University-Response-to-the-Draft-NIH-Biosafety-Policy.pdf

Description: Email Submission from: La Trobe University

La Trobe University Response to the Draft NIH Biosafety Policy for Research Involving Biohazards

La Trobe University supports NIH's objective of strengthening and modernising biosafety oversight and recognises the importance of maintaining robust, transparent and risk-based governance arrangements for research involving biohazards.

As an Australian university, La Trobe operates within an established regulatory framework that includes the Australian Gene Technology Scheme, biosecurity legislation, institutional biosafety committee oversight arrangements, and Australian/New Zealand standards governing microbiological safety and physical containment. These systems provide legally enforceable biosafety requirements and are supported by institutional governance, training, monitoring and incident management processes.

Our principal concern is that the draft policy may be interpreted as applying beyond NIH-funded research to broader institutional research activities that have no direct relationship with NIH funding. We encourage NIH to limit the scope of the final policy to NIH-funded research and activities that directly support, or are materially connected with, NIH-funded research.

We also encourage NIH to recognise equivalent biosafety outcomes achieved through mature host-country regulatory systems. Requiring international institutions to duplicate US-specific terminology, classifications, review processes, committee structures and reporting arrangements may create significant administrative burden without necessarily improving biosafety outcomes.

To support international engagement while maintaining appropriate accountability, NIH should establish a foreign-assurance or equivalency pathway for institutions operating within established national biosafety frameworks. Such an approach could allow institutions to demonstrate that domestic regulation and institutional oversight achieve outcomes comparable to NIH expectations without requiring wholesale duplication of US administrative requirements.

Additional guidance would be beneficial regarding the application of the policy to foreign recipients, collaborators and subrecipients, particularly where domestic legal obligations differ from NIH requirements. Guidance mapping Australian Physical Containment classifications to NIH Risk Groups and Biosafety Levels would also assist implementation.

La Trobe University supports strong, risk-based biosafety oversight and remains committed to meeting appropriate requirements for NIH-supported research. We encourage NIH to adopt a proportionate framework that provides assurance to NIH

while recognising effective host-country regulatory systems and avoiding unnecessary duplication for international institutions.

534. Andrea Ladd

I am responding: On behalf of myself

Name: Andrea Ladd

Name of Organization:

Type of Organization: Not Applicable

Role: Other

Role - Other: Biosafety professional and former researcher

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): N/A

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: N/A

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): N/A

3. Continued utility of Risk Groups: N/A

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): N/A

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: N/A

6. Other feedback relevant to this resource: N/A

Uploaded File: Ladd_personal-comments-on-draft-NIH-policy-and-templates.pdf

Description: Email Submission from: Andrea Ladd. A. Ladd personal comments on the draft NIH Policy

To: National Institutes of Health Office of Science Policy

From: Andrea N. Ladd, Ph.D., RBP (ABSA)

RE: Comments on the Draft NIH Biosafety Policy for Research Involving Biohazards

October 16, 2026

I am the Biological Safety Officer for an R1 institution and have spent the past decade in the biosafety profession. Before that, I was the principal investigator (PI) of a biomedical research laboratory for more than a decade. I have a PhD in cell biology and hold the Registered Biosafety Professional (RBP) credential from the American Biological Safety Association. **These comments are my own and do not represent the opinions of my current or past employers.**

During my 25 years as a researcher (including 3 years as an undergraduate, 5 years of graduate school, 6 years of postdoctoral training, and 11 years as PI), much of my research was directly or indirectly funded by the NIH. For decades the NIH has supported the training of the biomedical workforce and enabled biomedical innovations that save lives.

I applaud the NIH for seeking to modernize its biosafety and biosecurity framework by replacing the now dated *NIH Guidelines*, and for sincerely engaging with the biosafety and research communities as well as the public during this process.

This is a significant overhaul, not minor tweaks of the longstanding *NIH Guidelines*. There is much to laud in the draft NIH Biosafety Policy for Research Involving Biohazards and there is room for improvement. **I therefore urge the NIH to provide the opportunity for additional public comments on the next draft of the Biosafety Policy before it is finalized and institutions are directed to implement it.**

My specific comments on this draft are provided below.

<u>What the policy gets right:</u>

- Reinforcing institutional accountability for biosafety programs through the addition of the Biosafety Assurance statement
- Limiting the scope to biomedical research, which fits within the mission of the NIH
- Expanding the scope to include non-recombinant/synthetic nucleic acid-based biohazards such as wildtype pathogens and biological toxins
- Removing prescriptive containment levels and practices and empowering the Institutional Biosafety Committee (IBC) to apply local risk assessments
- Using risk groups (RGs) as a starting point for risk assessment, not the endpoint
- Creating a delegated review level for lower risk research

- Narrowing the circumstances when NIH approval is needed to those with greater uncertainty or higher risk
- Narrowing and more precisely defining when incidents must be reported to NIH
- Committing to NIH generating and publishing an Annual Incident Summary Report to identify trends that may guide safety training and incident prevention programs

Areas where improvement is needed:

- **The scope of the policy is unclear.** Section II defines the scope as limited to research involving known or potential risk to human health, but this is muddied throughout the policy by references to ecological and environmental risks and inclusion of RG1 organisms and transgenic animals at BSL1/ABSL1.
- **The timeline for implementation is too short.** Implementation of the new Biosafety Policy will require significant overhauls at many institutions, including revamped IBCs and committee workflows, biosafety protocol software updates, and new or expanded staffing models. Six months may fall within a single fiscal year, making it challenging to adjust budgets or allocate additional resources. This is particularly true for smaller institutions that cannot rapidly deploy resources and public schools that rely on state commitments.
- **Many key definitions are poor or missing.** Risk groups are mentioned throughout the policy but are not defined in it. GDMOs are mentioned but not defined. "Biological agent" should be changed to "Biohazardous agent", as not all biological materials cause human disease. A toxin is defined as a "protein or peptide … that causes harm in humans", but not all toxins are proteinaceous, and not all harmful proteins are toxins.
- **Biosafety Officers (BSOs) are given more responsibility without accompanying authority.** The NIH Biosafety Policy sets forth oversight responsibilities for the BSO (e.g., conducting inspections, investigating incidents), but does not require institutions to give BSOs the authority to correct problems that they identify. The policy does not define the qualifications for BSOs. Institutions are not even required to have a BSO unless they have research at BSL3/BSL4 or GDMOs. BSOs should be analogous to Institutional Officials that support IACUCs and oversee animal programs, with authority commensurate with their responsibilities.
- **Posting incident reports on a public website compromises personal privacy and endangers safety culture.** While I appreciate the NIH's attempts to improve transparency, publicly sharing incident reports will deter reporting. For smaller laboratories or those working in specialized areas, the inclusion of details such as PI name, specific research materials, and position titles will make it all too easy to identify individuals involved in incidents. This compromises privacy and makes it easier for nefarious actors to target individuals (e.g., animal rights extremists). The inclusion of treatment information can inadvertently reveal information about an individual's personal health status. Together, these considerations will create a safety culture in which unsafe conditions and practices go unreported and unaddressed out of fear of reprisal or adverse consequences.

- **Mandating use of specific templates adds administrative burden.** While I appreciate that the NIH is creating tools to aid implementation of the policy, requiring the use of specific templates does not allow institutions the flexibility to tailor implementation to fit existing processes and workflows. For example, many institutions use software programs to automate creation of IBC minutes. Requiring a specific template be used will mean either reprogramming software or manually creating the minutes. This adds burden without improving safety.
- **The NIH sets timelines for institutions but not for themselves.** Institutions are given six months to implement the new Biosafety Policy; the NIH intends to provide implementation resources but has made no commitment to have these available when the clock starts ticking. Institutions must submit initial incident reports within 24 hours and full incident reports within 30 days, while the NIH commits to no specific turnaround for reviewing and responding to incident reports, saying only that these will be done "in a timely manner". Requests to lower containment are also reviewed "in a timely manner" and no timeframe is given for publishing approved determinations. Why is the NIH not held to the same standards as the institutions they fund?
- **Delegated review shifts but does not reduce administrative burden.** Delegated review will allow the IBC to allocate more of its meeting time where it is needed most, the review and discussion of higher risk research. It does not, however, reduce the number of biosafety protocols that researchers need to create and institutions must process, review, and track. The *NIH Guidelines* specifically described exemptions for certain low-risk materials, but if these exist under the draft Biosafety Policy, they are no longer explicitly called out.

<u>Summary of my recommendations:</u>

- Clarify the scope of the policy, preferably by explicitly limiting it to research that poses a <u>direct</u> known or potential risk to human health (e.g., pathogen or vector of human disease)
- Extend the timeline for implementation to two years
- Every institution that has research with biohazardous materials subject to the policy should be required to have a BSO(s)
- BSOs should be given the authority to enforce the NIH and institutional policies related to biosafety and biosecurity
- Replace the requirement to post individual incident reports on a public website with a requirement to post aggregated and anonymized incident data
- Provide templates but make their use optional
- Provide implementation guidance at go-live, including online FAQs, a monitored email address and dedicated phone number for live assistance
- Set a standard timeline for the NIH to respond to incident reports and requests to set or lower containment, including publication of these determinations
- Explicitly exclude lower risk research and research that falls under the oversight of another federal agency to reduce unnecessary administrative burden, including:

- Genetically modified organisms at BSL1/ABSL1, especially common animal models such as laboratory-bred rodents, fish, frogs, fruit flies, and non-parasitic nematodes
- Recombinant RG1 organisms that are not modified such that they pose a risk to human health, especially common host vector systems used for cloning and protein purification such as RG1 *E. coli* and *S. cerevisiae*
- Genetically modified cell lines that do not produce and have not been administered biohazardous agents
- *Ex vivo* work with isolated plasmids or constructs that do not pose a risk to human health outside of an organism
- Human-derived materials covered by the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030
- Select agents and toxins covered by 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

Thank you for the opportunity to provide feedback on the draft NIH Biosafety Policy.

Sincerely,



Andrea N. Ladd, Ph.D., RBP (ABSA)

535. Oak Ridge National Laboratory

I am responding: On behalf of an organization

Name: Anuj Kapadia

Name of Organization: Oak Ridge National Laboratory

Type of Organization: Government Agency

Role: Organizational Official

Date Submitted: 10/20/2026

Domain of research most important to you or your organization (e.g. cognitive neuroscience, infectious epidemiology): Biosecurity, Biodefense, Computational drug discovery

1. Appropriateness of the scope of the new policy, including the definition of biohazards for the purpose of oversight and any inadvertent gaps in oversight that should be addressed: ORNL supports expanding oversight beyond recombinant and synthetic nucleic-acid research. Biological risk can arise from wild-type pathogens, toxins, prions, serial passage, reassortment, directed evolution, and other methods not captured by the current framework. ORNL already reviews biological hazards under DOE requirements, including 10 CFR 851, Appendix A, Section 7, using BMBL principles.
However, the definition should be limited to a reasonably foreseeable, non-de minimis risk under the proposed experimental conditions. For example, genetic modification or use of a toxin should not automatically trigger substantive review without considering pathogenicity, dose, route, scale, replication competence, environmental stability, and available countermeasures.
NIH should recognize equivalent oversight by DOE, defense and national-security agencies, CDC/USDA, and other federal authorities. Receipt of any NIH funding should require an adequate institutional biosafety program but should not automatically give NIH project-level authority over classified, controlled, proprietary, or non-NIH-sponsored research. The cognizant federal agency should serve as the lead authority.
The policy should also address AI-biotechnology convergence. Purely computational research should not automatically fall under IBC oversight, but review may be warranted when computational work is linked to creating or validating a biological agent or producing an actionable information hazard. NIH should coordinate with the July 2026 USG high-risk life-sciences policy and provide guidance on biological design data, model access, third-party AI systems, cybersecurity, export controls, and foreign-national access.

2. Appropriateness of tiered oversight and calibration to risk (i.e., federal vs local): A tiered system is appropriate. Local IBCs should remain the primary reviewers because they understand institutional facilities, personnel, procedures, and emergency capabilities. Delegated review is appropriate for well-characterized, lower-risk work; full IBC review should focus on significant or uncertain hazards; and federal review should be reserved for novel or emerging agents, initial reductions in containment for RG3/RG4 agents, and research with potentially high-consequence implications.
The final policy should establish a lead-federal-agency and mutual-recognition principle. Research reviewed under equivalent DOE, defense, intelligence-community, Select Agent, or other federal

requirements should not undergo duplicative NIH approval. The cognizant sponsor should be primary for approval, enforcement, incident response, and information control.
For classified or controlled work, NIH should permit review by the sponsoring agency or an appropriately cleared institutional body and accept an unclassified certification in place of protected project details. Defined review timelines, expedited review for urgent public-health or national-security work, an appeal process, and a transition period for existing projects are also needed.

3. Continued utility of Risk Groups: Risk Groups and Biosafety Levels are complementary, not competing. RG provides a useful baseline assessment of an agent's intrinsic hazard. BSL describes the facilities, practices, equipment, and controls necessary to perform a specific activity safely and is therefore an outcome of the experiment-specific risk assessment.
NIH should retain RG classifications as an initial screen while requiring a BMBL-consistent assessment of the agent, modifications, proposed manipulations, route of exposure, aerosol or sharps risk, scale, animal use, environmental stability, available countermeasures, and scientific uncertainty.
For genetically modified agents, the highest RG associated with a source sequence may be a conservative screening consideration but should not automatically determine containment. A short, nonfunctional sequence from an RG3 agent does not necessarily give an RG1 host the same risk profile. Conversely, low-risk components may combine to produce a higher-risk phenotype. Functional properties and experimental context should determine the final BSL. NIH should provide worked examples for attenuated strains, replication-defective vectors, directed evolution, synthetic constructs, and AI-generated (or reverse-engineered) sequences.

4. Mechanisms to encourage and accommodate voluntary compliance for research not subject to the policy (e.g., at non-NIH funded institutions): NIH should encourage voluntary compliance through assistance and incentives rather than unfunded mandates. Useful mechanisms include model policies, decision tools, training, technical consultation, shared or external IBCs, transition funding, and recognition of equivalent federal or accredited biosafety programs.
Voluntary near-miss reporting should be confidential, de-identified, and protected from enforcement or routine public disclosure unless the event involves a material exposure, release, laboratory-acquired infection, or comparable risk. A national laboratory already operating under 10 CFR 851 and the BMBL should be able to demonstrate equivalent compliance without creating a separate NIH-specific system.

5. Comments on Draft Incident Reporting and Draft Meeting Minutes Templates: Standardized templates can improve consistency, but official regulatory records should be separated from public communications.
For incident reporting, 24-hour notification is appropriate for laboratory-acquired infections, consequential releases, significant high-containment failures, and material noncompliance. Lower-risk events managed locally should remain institutional records rather than being individually posted online. Public disclosure of minor events could discourage reporting while obscuring genuinely important incidents.
For NIH-reportable incidents, institutions should submit a complete official report but publish only a de-identified, security-reviewed summary. Public reports should not be required to identify the PI, agent, construct, sponsor, facility, exposure pathway, or security vulnerability when disclosure could compromise national security, personnel safety, export controls, intellectual property, or sponsor confidentiality.
Similarly, full IBC minutes should document the committee's review, while the public version should be a

sanitized summary demonstrating that risks and controls were appropriately evaluated. Absolute prohibitions on redacting PI names or other fields are inappropriate. Classified or controlled work should be reported through sponsor-approved channels, with NIH accepting an unclassified certification or sanitized summary. These protections should align with the July 2026 USG policy, which expressly protects national-security, research-security, business-sensitive, and legitimate intellectual-property information.

6. Other feedback relevant to this resource: Before implementation, NIH should provide:
• Decision trees and examples defining covered, delegated, full-IBC, federal-review, and excluded research.
• Crosswalks among the NIH policy, 10 CFR 851, BMBL, Select Agent requirements, OSHA, export controls, and the July 2026 USG high-risk life-sciences policy.
• Lead-agency, reciprocity, and conflict-resolution procedures.
• Processes for classified, CUI, export-controlled, proprietary, and sponsor-restricted research.
• Guidance on AI-assisted biological design, model weights, training data, cloud AI services, foreign-national access, cybersecurity, and information hazards.
• A process for limiting data or model release when open disclosure could enable harmful biological design or compromise national or economic security.
• Examples translating RG, genetic modification, experimental activity, and uncertainty into BSL decisions.
• Clear thresholds for immediate NIH reporting, local review, near-miss reporting, and events requiring no formal report.
• Uniform standards for security, privacy, proprietary, and sponsor review before public disclosure.
• Guidance on aligning IBC responsibilities with the Institutional Review Entity required by the USG high-risk-research policy.
• Procedures for multisite studies, external IBCs, user facilities, and subcontractors.
• A reasonable transition period, grandfathering of existing approvals, defined NIH response times, and implementation support.
The final framework should create a common national standard while allowing institutions to satisfy it through existing, effective biosafety programs. Success should be measured by improved risk identification and incident prevention, not by the volume of reviews or public records generated.