

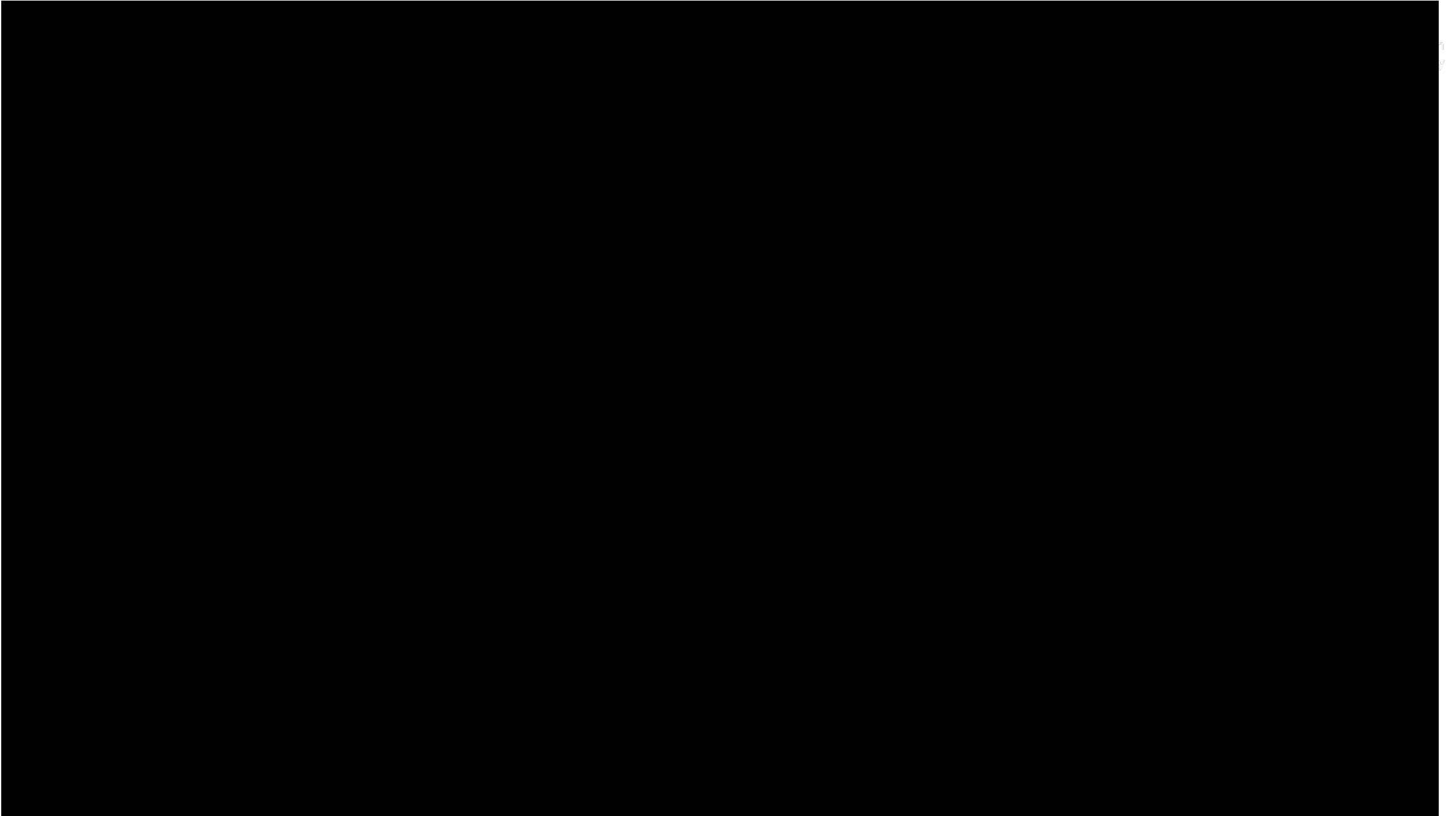


National Institutes of Health
Turning Discovery Into Health

Biosafety Modernization Initiative

Listening Session 6

February 26, 2026



NIH Biosafety Modernization Initiative

Proposed Timeline

Phase I

Fall 2025 – Winter 2026

- Engage the public through regional listening sessions and stakeholder events

Phase III

Summer – Fall 2026

- Assess Draft Policy feedback
- Refine policy
- Assess guidance needs

Phase II

Spring – Summer 2026

- Synthesize information heard from public engagements
- Publish Draft Policy for public comment

Phase IV

Fall 2026

- Publish Final Policy
- Release community-driven guidance
- Launch rigorous outreach and education efforts

First Things First

NIH Goals:

- Develop a risk-based biosafety framework that allow institutions to allocate resources effectively.
- Develop a 21st century biosafety oversight paradigm that is transparent, adaptive, and accountable.
- Empower IBCs and reinforce consistency with IRBs and IACUCs.
- Work with our government partners.

Keep in Mind:

- This is not a re-write of the NIH Guidelines. Building upon our existing strong foundation, we are developing a new policy framework, so vital research can move forward under appropriate biosafety conditions.
- NIH will continue to strengthen its partnership with IBCs and biosafety professionals to ensure rigorous oversight that is commensurate with the risks posed.

SPOILER ALERT: WE CANNOT DO THIS WITHOUT YOUR HELP!!!!!!

Science and Technology Have Evolved: Biosafety Policy and Oversight Need to Keep Pace

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules have served as the foundation for biosafety practices for 50 years and have been adopted across Federal Departments and Agencies
- Biosafety risks don't exclusively depend on the technique used (e.g., recombinant/synthetic nucleic acids)
- USG needs a **risk-based, coordinated policy and oversight system**

NIH, in partnership with IBCs and the public, is well positioned to usher in a new era of oversight to ensure the safe conduct of research.

Biosafety Policy for the 21st Century

CURRENT SCOPE OF NIH GUIDELINES



- **Technique-based**, focus on recombinant and synthetic nucleic acid molecules
- Includes plants, microbes for environmental remediation, vaccine/gene therapy
- Some covered research under purview of other agency authorities (e.g., USDA, FDA)

POTENTIAL FUTURE SCOPE OF NIH BIOSAFETY POLICY



- **Risk-based**, expand to include wild type agents and other possible biohazards
- Focus on NIH-relevant contained **biomedical** laboratory research
- Resources allocated for oversight are calibrated to risk posed

We Need Your Feedback!

To achieve the goal of modernized oversight that is **tiered based on risk-**

We are particularly interested in hearing opinions on:

- **Roles and responsibilities** of institutions, IBCs, investigators, and NIH
- Ways to **strengthen coordination** between IBCs and other institutional review bodies
- Options for **review and approval of lowering requests**

NOTE: All draft options presented here are a starting point; we welcome individual input on any topics or options that you think should be considered. NIH will consider all comments received.

Thoughts on Proposed Options?

Opportunities to improve IBC functions and advance compliance and transparency

- **Roles and responsibilities** of institutions, IBCs, investigators, and NIH
 - *Incident reporting and threshold for reporting (e.g., laboratory acquired infections, BL3 or 4 research)*

- Possible ways to **strengthen coordination** between IBCs and other institutional review bodies
 - *Infrastructure and communication*
 - *Liaison members between committees*

- Options for **review and approval of lowering requests**
 - *Requests to lower containment for research involving RG3 or RG4 agents*
 - *NIH reviews and approves all requests*
 - *Eligible for IBCs to approve subsequent requests after initial NIH approval*
 - *Requests to lower containment from BL2 to BL1*
 - *NIH review and approval*
 - *IBC review and approval*

How Can You Help Right Now?

Visit our website to find the latest information on NIH efforts to modernize and strengthen biosafety oversight

<https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/>

On-demand commenting using the biosafety badge/widget

<https://osp.od.nih.gov/help-modernize-and-strengthen-the-oversight-of-biosafety/>

