Table of Changes from the Current NIH Guidelines to the Draft NIH Policy for Research Involving Biohazards

The resource presented below is aimed at assisting stakeholders in understanding the changes being proposed in the Draft NIH Policy for Research Involving Biohazards. While the table does not list every change being proposed, it does summarize the most significant changes being proposed.

This resource is a quick reference guide and should not be construed as a substitute for reviewing the draft policy. Please also note that NIH is not accepting public comment on this resource. The documents that NIH is seeking feedback on are:

- Draft NIH Policy for Research Involving Biohazards
- Required Template for Meeting Minutes
- Required Template for Reporting Incidents and Accidents

Comments on the above documents can be made through the NIH comment portal found at: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards/

Comments will be accepted until **October 19, 2026**.

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	CURRENT REQUIREMENTS	PROPOSED REQUIREMENTS
AREAS OF SIGNIFICANT CHANGE	**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)**	**Draft NIH Biosafety Policy for Research Involving Biohazards (Biosafety Policy)**
Scope	The NIH Guidelines are a term and condition of award and apply to NIH-supported institutions that conduct research with recombinant or synthetic nucleic acid molecules.	The NIH Biosafety Policy would continue to be a term and condition of award and would apply to NIH-supported institutions conducting biomedical research in laboratory settings involving known or potential biohazards. The Policy defines research involving biohazards as involving known or potential risk to human health and any of the following: 1. Wild type biological agents 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. 4. Cells or organisms containing 1, 2 or 3 above.
Institutional Submissions to NIH (Registrations/ Assurances)	Institutions are required to register an appropriately constituted Institutional Biosafety Committee (IBC) with NIH. Institutions must then file annual updates detailing any changes to the IBC.	The Authorized Organizational Representative of the institution will be required to submit a written assurance that the institution will comply with the Policy. As part of this assurance, the institution must make available information about the policies and procedures the institution has in place. Assurances will require NIH approval and will be valid for a period of four years. Institutions will no longer be required to provide annual rosters to NIH but must ensure that a current IBC roster is maintained on the institution's website.
IBC Functions (Incident Reporting)	Institutions must report significant problems, violations or significant research-related accidents and illnesses to NIH within thirty days. Overt exposures occurring under Biosafety Level/Animal Biosafety Level (BSL/ABSL)-2	Institutions must report to NIH incidents involving: • confirmed or potential laboratory acquired infection (LAI), • any loss of containment/release that has the potential for community risk

	conditions require immediate NIH notification, as well as overt or potential exposures occurring under BSL/ABSL-3 or BSL/ABSL-4 containment. Incident reports are publicly available through the Freedom of Information Act.	• any incident at BSL/ABSL-3 or BSL/ABSL-4 (including potential exposures) • incidents at BSL/ABSL-2 involving agent-specific treatment beyond basic first aid • any compliance violations at any BSL/ABSL such as failure to obtain or maintain IBC approval for research Lower risk incidents or accidents are to be reported to the appropriate institutional offices and appropriately addressed by the institution, but do not require submission to NIH. Examples of these types of incidents include, but are not limited to: • Any incident involving animal research subject to this policy that is conducted at BSL/ABSL-1 or BSL/ABSL-2 (e.g., bite, scratch, escape or improper disposition) • Any incident at BSL/ABSL-1 or BSL/ABSL-2 that does not involve agent-specific medical treatment when first aid is administered . All reports, whether reportable to only the institution or to NIH, must be posted on a public-facing website of the institution.
Categories of Research (Lowering of Containment)	IBCs must obtain NIH approval before lowering the containment level for any research projects.	Initial requests to lower containment for research involving wild type or genetically modified Risk Group (RG)3 or RG4 biological agents must be approved by NIH. IBC approval is required for lowering the containment for wild type or genetically modified RG2 biological agents. 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.

Delegated Review of Research	Delegated review is not permitted.	Delegated review, where an IBC member or a subset of IBC members approves research on behalf of the IBC, is permitted for specific classes of experiments including: • Research involving RG2 wild-type biological agents • Research with genetically modified RG1 biological agents • Research with transgenic organisms conducted at BSL/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 toxin proteins not on the select agent list
Clinical Research	IBCs must approve all experiments involving the transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants	IBCs must approve 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 • RG2 or higher wild type biological agents
Research Involving Genetically Modified Plants	Certain research with genetically modified plants requires IBC approval prior to initiation. Other experiments require only notification to the IBC before beginning.	Genetically modified plants and plant pathogens that do not cause human disease are not covered under the proposed Biosafety Policy.
Required Documentation	Institutions may use any format to satisfy the record keeping requirements pertaining to incident reporting. NIH developed a template that is recommended when an institution is reporting incidents to NIH.	To ensure consistency and information quality, institutions will be required to use the meeting minutes and incident reporting templates found in Appendix A and Appendix B of the Biosafety Policy.